FEDERAL REGISTER

Vol. 85 Friday,

No. 234 December 4, 2020

Pages 78197–78698

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 85 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**

General online information **202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Contents

Federal Register

Vol. 85, No. 234

Friday, December 4, 2020

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register

Vol. 85, No. 234

Friday, December 4, 2020

DEPARTMENT OF ENERGY

10 CFR Part 1021

[DOE–HQ–2020–0017]

RIN 1990–AA49

National Environmental Policy Act Implementing Procedures

AGENCY: Office of the General Counsel, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE or the Department) is updating its National Environmental Policy Act (NEPA) implementing procedures pertaining to authorizations issued under the Natural Gas Act (NGA). These changes will improve the efficiency of the DOE decision-making process by saving time and expense in the NEPA compliance process and eliminating unnecessary environmental documentation for these actions that DOE has determined normally do not have significant effects.

DATES: This final rule is effective January 4, 2021.

ADDRESSES: Documents relevant to this rulemaking are posted on the Federal eRulemaking Portal at *https://beta.regulations.gov/* (*Docket: DOE–HQ–2020–0017*). Documents posted to this docket include: The Notice of Proposed Rulemaking issued on May 1, 2020 (85 FR 25340); DOE's May 2020 Technical Support Document, which provides additional information; a ''redline/strikeout'' (markup) file of affected sections of the DOE NEPA regulations indicating the proposed changes; the comments received on the proposed changes; this final rule; and DOE's November 2020 Technical Support Document. Documents related to this rulemaking also are available on DOE's NEPA website at *https://energy.gov/nepa.*

FOR FURTHER INFORMATION CONTACT: Mr. Mark J. Matarrese, Office of Fossil Energy, *Mark.Matarrese@hq.doe.gov,* 202–586–0491; Edward Le Duc, Office of Assistant General Counsel for Environment, *Edward.LeDuc@hq.doe.gov,* 202–586–4007.

SUPPLEMENTARY INFORMATION:

I. Background

DOE is responsible for authorizing exports of domestically produced natural gas to foreign countries under section 3 of the NGA.[1] NEPA requires agencies to consider the environmental impacts of proposed major Federal actions as part of their decision-making process.[2] DOE must comply with NEPA's requirement for an environmental review before reaching a final decision on applications to export natural gas to countries with which the United States does not have a free trade agreement requiring national treatment for trade in natural gas (non-FTA countries).

The Council on Environmental Quality (CEQ) regulations (40 CFR parts 1500–1508) implementing NEPA require agencies to develop their own NEPA implementing procedures, as necessary, to apply the CEQ regulations to their specific programs and decision-making processes.[3] CEQ revised its NEPA regulations in July 2020.[4] Through this rule, DOE is revising its NEPA regulations[5] consistent with the CEQ regulations that allow agencies to identify in their agency procedures categories of actions that normally do not have significant effects, and with the legal principle that potential environmental effects to be considered by an agency under NEPA do not include effects that the agency has no authority to prevent.

In particular, DOE makes these revisions because (1) DOE is required by section 3(c) of the Natural Gas Act[6] to authorize liquefied natural gas (LNG) exports to FTA countries and lacks discretion with respect to such approvals and (2) DOE's review of applications for LNG exports to non-FTA countries is limited to consideration of effects that are reasonably foreseeable and have a sufficiently close causal connection to the granting of the export authorization.[7] As set forth below, DOE revises categorical exclusion (CX) B5.7 to focus exclusively on the analysis of potential environmental impacts resulting from activities occurring at or after the point of export, which are within the scope of DOE's export authorization authority under the NGA.[8] Such impacts begin at the point of export and are limited to the marine transport effects.[9]

DOE authorization also is required for imports of natural gas under section 3(a) of the NGA. However, section 3(c) of the NGA was amended by section 201 of the Energy Policy Act of 1992[10] to require that applications to authorize the import of natural gas be ''deemed consistent with the public interest, and . . . granted without modification or delay.'' This requirement leaves DOE with no discretion in its approvals of LNG imports, as they are deemed to be in the public interest. Accordingly, DOE is removing the reference to authorizations to import natural gas from its NEPA regulations, consistent with the legal principle that an agency is not required to prepare a NEPA analysis when it has no discretion in its action.[11]

[1] 15 U.S.C. 717b. Section 3(a) of the NGA requires DOE to issue an order authorizing natural gas exports unless it finds that such an order ''will not be consistent with the public interest.''

[2] 42 U.S.C. 4332(2)(C).

[3] 40 CFR 1507.3.

[4] 85 FR 43304 (July 16, 2020).

[5] 10 CFR part 1021.

[6] Section 3(c) requires DOE to authorize applications for the export of natural gas to nations with which there is a free trade agreement (FTA countries), requiring that all such exports be ''deemed consistent with the public interest, and . . . granted without modification or delay.''

[7] 40 CFR 1508.1(g); *see also Dep't of Transp.* v. *Pub. Citizen,* 541 U.S. 752 (2004); *Sierra Club* v. *Fed. Energy Regulatory Comm'n,* 827 F.3d 36 (D.C. Cir. 2016).

[8] This scope of analysis is consistent with decisions in recent years of the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit), which recognize that DOE ''maintains exclusive jurisdiction over the export of natural gas as a commodity.'' *Sierra Club* v. *Fed. Energy Regulatory Comm'n,* 827 F.3d at 40. Specifically, the D.C. Circuit has observed that the Federal Energy Regulatory Commission (FERC) has an obligation to comply with the NGA and NEPA with respect to its decisions to authorize the construction of LNG terminals, whereas DOE has an independent obligation ''to consider the environmental impacts of its export authorization decision under NEPA and determine whether it satisfie[s] the Natural Gas Act's 'public interest' test.'' *Sierra Club* v. *U.S. Dep't of Energy,* 867 F.3d 189, 192 (D.C. Cir. 2017).

[9] DOE defines export activities as starting at the point of delivery to the export vessel, and extending to the territorial waters of the receiving country.

[10] Energy Policy Act of 1992, Public Law 102–486, 106 Stat. 2776 (Oct. 24, 1992).

[11] 40 CFR 1501.1(a)(5), and 40 CFR 1508.1(q)(1)(ii); 10 CFR 1021.104(b) (defining ''Actions'' requiring NEPA review but specifically excluding ''purely ministerial actions with regard to

Continued

A. What parts of DOE's NEPA regulations is DOE amending?

DOE's NEPA regulations list classes of actions normally associated with each level of NEPA review.[12] This final rule revises the five classes of actions regarding applications to import or export natural gas to a non-FTA country. These are two CXs: B5.7 (Import or export of natural gas, with operational changes) and B5.8 (Import or export of natural gas, with new cogeneration powerplant); one class of actions normally requiring an EA: C13 (Import or export natural gas involving minor new construction); and two classes of action normally requiring an EIS: D8 (Import or export of natural gas involving major new facilities) and D9 (Import or export of natural gas involving major operational change).[13]

B. What revisions is DOE making?

DOE is revising the classes of action in its NEPA regulations regarding authorizations under section 3 of the NGA for non-FTA countries, consistent with the CEQ regulations,[14] and the legal principle enunciated in *Public Citizen* and *Sierra Club*[15] that potential environmental effects considered under NEPA do not include effects that the agency has no authority to prevent. DOE's discretionary authority under Section 3 of the NGA is limited to the authorization of exports of natural gas to non-FTA countries. Therefore, DOE need not review potential environmental impacts associated with the construction or operation of natural gas export facilities because DOE lacks authority to approve the construction or operation of those facilities. DOE's review is properly focused on potential environmental impacts resulting from the exercise of its NGA section 3 authority. These potential impacts would occur at or after the point of export to non-FTA countries.

Accordingly, DOE is revising the scope of CX B5.7 by deleting the reference to operation of natural gas facilities. The revised B5.7 includes a new statement that the scope includes any ''associated transportation of natural gas by marine vessel,'' which would be the only source of potential environmental impacts resulting from DOE's decision regarding authorizations under section 3 of the NGA. Based on prior NEPA reviews and technical reports,[16] DOE has determined that transport of natural gas by marine vessel normally does not pose the potential for significant environmental impacts.

DOE also is removing the reference to import authorizations from B5.7 because section 3(c) of the NGA directs that authorization requests to import natural gas, as described in NGA section 3(b), ''shall be granted without modification or delay.'' DOE is not required to prepare NEPA analysis when it has no discretion in its action.[17]

Finally, DOE is removing and reserving CX B5.8 and classes of action C13, D8, and D9 because these actions are outside the scope of DOE's authority or are covered by the revised CX B5.7.

C. How does DOE make a CX determination?

The revised CX B5.7 is subject to the same conditions as other CXs listed in appendix B to subpart D of DOE's NEPA regulations. Before a proposed action such as an export authorization may be categorically excluded, DOE must review the proposed action in accordance with 10 CFR 1021.410 and determine that application of a CX is appropriate.

In addition, to fit within a class of actions in appendix B (including B5.7), a proposed action must satisfy certain conditions known as ''integral elements.''[18] These conditions ensure that a proposed action would not have the potential to cause significant environmental impacts—for example, due to a threatened violation of applicable environmental, safety, and health requirements.

II. Comments Received and DOE's Responses

DOE invited interested persons to submit comments on the Notice of Proposed Rulemaking and supporting information during a public comment period that ended on June 1, 2020.[19] DOE received 16 comment letters from a number of parties, including environmental organizations, industry groups, and individuals. The Notice of Proposed Rulemaking and comments DOE received are available on the Federal eRulemaking Portal as described in the **ADDRESSES** section of this final rule.

DOE has evaluated the comments it received. In this section, DOE discusses the relevant, substantive comments and provides its responses to those comments. Some commenters raised issues that are outside the scope of the Notice of Proposed Rulemaking, because they do not speak to DOE's NEPA obligations or to the subject of the proposed rule. These issues include fossil energy extraction and use, construction of LNG pipelines and terminals, expanding use of renewable energy generally, moving to a carbon-neutral energy mix, and whether DOE's public interest analysis under the NGA has an environmental component.

A. General Comments

Some commenters expressed support for DOE's proposed changes. For example, some commenters remarked that the proposed changes will reduce redundancy, delay, and regulatory uncertainty. DOE acknowledges these comments. Some commenters opposed the proposed rulemaking, stating, for example, that DOE had provided no evidence the proposed changes would improve efficiency. Based on its experience reviewing and considering the potential environmental effects of many requests for export authorization, DOE believes that the proposed changes will improve the efficiency of DOE's decision-making process by focusing its NEPA review on those activities that are within DOE's authority under the NGA.

Some commenters requested that DOE extend the public comment period on the Notice of Proposed Rulemaking. To support their request, these commenters referred to impacts of the proposed changes on agency environmental review obligations and to circumstances created by the COVID–19 national emergency. DOE believes that the thirty-day comment period provided for this proposed rulemaking provided an adequate opportunity for public comment for these limited revisions to its implementing procedures. DOE recognizes the substantial disruption and hardship brought about by the COVID–19 pandemic. However, the proposed rule was widely available in a variety of accessible formats, and

which DOE has no discretion,'' such as ''ministerial actions to implement congressionally mandated funding for actions not proposed by DOE and as to which DOE has no discretion''); *Dep't of Transp.* v. *Pub. Citizen,* 541 U.S. at 768–770; *Sierra Club* v. *Fed. Energy Regulatory Comm'n,* 827 F.3d at 40; *Citizens Against Rails-to-Trails* v. *Surface Transp. Bd.,* 267 F.3d 1144, 1151 (D.C. Cir. 2001).

[12] There are three levels of NEPA review established in the (CEQ NEPA implementing regulations (40 CFR parts 1500–1508)—categorical exclusion, environmental assessment (EA), and environmental impact statement (EIS) each involving different levels of information and analysis.

[13] *See* 10 CFR part 1021, subpart D.

[14] 40 CFR 1508.1(g)(2).

[15] *Dep't of Transp.* v. *Pub. Citizen,* 541 U.S. 768–770; *Sierra Club* v. *Fed. Energy Regulatory Comm'n,* 827 F.3d 40 (D.C. Cir. 2016).

[16] U.S. Dep't of Energy, Technical Support Document, Notice of Final Rulemaking, National Environmental Policy Act Implementing Procedures (10 CFR part 1021) (Nov. 2020) [hereinafter Technical Support Document].

[17] *Supra* note 11.

[18] 10 CFR part 1021, subpart D, Appendix B, paragraphs (1) through (5).

[19] Dep't of Energy, National Environmental Policy Act Implementing Procedures, Notice of Proposed Rulemaking and Request for Comment, 85 FR 25340 (May 1, 2020).

comment submission was available through the Federal eRulemaking Portal and postal mail. It is important throughout this pandemic that DOE continue its mission, particularly in areas that contribute to strengthening the United States' economy.

B. Comments Regarding the NEPA Process and Standards for Developing a CX

I. Environmental Documentation Supporting Decisions Made Pursuant to DOE's Statutory Authority

Some commenters objected to use of a CX as proposed, stating that NEPA reviews are not ''unnecessary environmental documentation.'' A CX does not eliminate NEPA review. Rather it is a form of NEPA review that allows agencies to focus their resources on information pertinent to the agency's decision-making authority and related to potentially significant environmental impacts. In implementing the revised CX, DOE will consider whether an extraordinary circumstance is present such that an EA or EIS will be required.[20] DOE will also document its determination that application of the CX is appropriate. DOE's use of the phrase ''unnecessary environmental documentation'' is a reference to DOE's prior practice of considering the potential environmental effects from activities that are beyond its decision-making authority, such as LNG terminal construction and operation. In virtually all of its recent LNG export proceedings, DOE has referenced in its export orders the environmental documents prepared by the Federal Energy Regulatory Commission (FERC).[21] FERC, not DOE, reviews the potential environmental impacts of the construction and operation of the LNG terminals. Under the revised CX, DOE's NEPA review is tailored to its statutory authority and will not unnecessarily duplicate the documents that FERC or other agencies prepare under their statutory authorities.

II. Scope of ''Export Activities''

One commenter suggested that DOE should expand the definition of ''export'' to include operations required for the export process. DOE acknowledges the comment and notes that the statutory term ''export'' is not defined in the NGA. However, in adjudications under NGA section 3(a), DOE has construed an ''export'' of LNG from the United States as occurring ''when the LNG is delivered to the flange of the LNG export vessel.'' [22] Therefore, DOE believes it is appropriate for its NEPA review of natural gas export applications to consider the potential environmental impacts starting at the point of delivery to the export vessel, and extending to the territorial waters of the receiving country. This is referred to in the revised CX as export of natural gas under section 3 of the Natural Gas Act and any associated transportation of natural gas by marine vessel.

III. Criteria for Establishing a CX

Some commenters expressed concern that DOE did not meet the standard for establishing a CX and should have prepared an EA or an EIS for this rulemaking. These commenters stated that DOE (i) did not adequately consider the potential significance of environmental impacts resulting from this rulemaking, (ii) must analyze cumulative impacts of this rulemaking, and (iii) segmented consideration of natural gas exports from other connected actions in promulgating this rule.

DOE has met its obligations under NEPA. As noted in the Review Under National Environmental Policy Act sections of the Notice of Proposed Rulemaking and this final rule, the CEQ regulations do not direct agencies to prepare an EA or EIS before establishing agency procedures that supplement the CEQ regulations to implement NEPA.[23] CEQ regulations provide that an agency, when establishing a CX, must ''consult'' with CEQ for input regarding conformity with CEQ regulations and NEPA before publishing new NEPA procedures in the **Federal Register** for comment.[24] DOE has complied with this requirement.

Nevertheless, to support its decision, DOE did engage in an analysis to properly assess the potential significance of actions included in the revised CX B5.7. This analysis included a detailed review of technical documents regarding potential effects associated with marine transport of LNG. These documents are included in the Technical Support Document and support DOE's conclusion that potential environmental effects associated with marine transport, the only reasonably foreseeable environmental impacts associated with DOE natural gas export authorizations, are minimal.

Commenters asserted that DOE does not meet the standard for establishing a CX because it impermissibly segments natural gas exports from other connected actions, arguing that FERC's approval of export facilities is a ''connected action'' to DOE's export approval that must be considered as part of DOE's NEPA review. The CX adopted in this final rule follows the Supreme Court's holding in *Public Citizen* [25] and the current CEQ NEPA regulation at 40 CFR 1501.9(e)(1) regarding the circumstances in which ''connected actions'' must be analyzed. According to *Public Citizen* and the current CEQ NEPA regulations, a ''but for'' causal relationship is insufficient to make an agency responsible for a particular effect under NEPA.[26] Accordingly, DOE's export authorizations and the construction and operation of export facilities do not have a sufficient causal connection to be considered connected actions. FERC has exclusive statutory authority to approve construction and operation of natural gas export facilities. DOE has no authority to approve construction or operation of such facilities, and thus there is no DOE decision to be informed by a NEPA analysis. The only decision for which DOE has authority is with respect to the export of the commodity itself. DOE's and FERC's approval actions are not interdependent.[27] Therefore, DOE need

[20] 40 CFR 1501.4(b).

[21] In most cases, facility approval falls under FERC jurisdiction. In some cases involving offshore export facilities, the United States Maritime Administration (MARAD), rather than FERC, has statutory authority to approve facility construction and operation. Less commonly, where MARAD lacks jurisdiction, the Bureau of Ocean Energy Management (BOEM) would issue approval. DOE's practice was to adopt the NEPA record established by the authorizing agency for the facility.

[22] *See Kuhali* v. *Reno,* 266 F.3d 93, 104 (2d Cir. 2001) (citing legal definitions of ''export'' including those in Black's Law Dictionary 600 (7th ed.1999) (''to send or carry abroad''), ''as well as with the common usage of the term, *e.g.,* Webster's New Collegiate Dictionary 400 (1981) ('to carry or send (as a commodity) to some other place (as another country).' ''). This suggests that the ''export'' is limited to the action of transporting natural gas products from the U.S. to the receiving country, and that export activities therefore do not begin before the act of transporting the product overseas is initiated.

[23] *Heartwood, Inc.* v. *U.S. Forest Service,* 73 F. Supp. 2d 962, 972–73 (S.D. Ill. 1999), *aff'd,* 230 F. 3d 947, 954–55 (7th Cir. 2000) (upholding the determination that establishing agency NEPA procedures does not require an EA or an EIS).

[24] 40 CFR 1507.3(b).

[25] *Pub. Citizen,* 541 U.S. 767–768.

[26] *Pub. Citizen,* 541 U.S. 767 (''Respondents must rest, then, on a particularly unyielding variation of 'but for' causation, where an agency's action is considered a cause of an environmental effect even when the agency has no authority to prevent the effect. However, a ''but for'' causal relationship is insufficient to make an agency responsible for a particular effect under NEPA and the relevant regulations.''); *see also* 40 CFR 1508.1(g).

[27] U.S. Dep't of Energy, Addendum to Environmental Review Documents Concerning Exports of Natural Gas from the United States, at 1 (Aug. 2014) (citing Freeport LNG Expansion, L.P.

Continued

not consider effects associated with the construction and operation of natural gas export facilities under NEPA.

To the extent that commenters rely on *Sierra Club* v. *Bosworth* [28] to support the concerns raised above, this reliance is misplaced. As described in the paragraphs that follow, the facts of *Bosworth* are not analogous to this rulemaking.

With regard to scoping, DOE notes that *Bosworth* pertains to an action taken by the U.S. Forest Service. According to the Forest Service NEPA Handbook, scoping was required for all Forest Service proposed actions, including those that would be categorically excluded.[29] DOE has no similar requirement in its regulations, and the CEQ regulations require scoping only after a decision has been made to prepare an EIS.[30] Since an EIS is not required to establish NEPA procedures under CEQ or DOE regulations or applicable case law, scoping was not a prerequisite for the promulgation of this rule.

Some commenters cited *Bosworth* when raising their concern that DOE had failed to adequately review potential cumulative impacts associated with promulgation of the CX, or that DOE has failed to draft the CX with sufficient specificity to distinguish between actions having significant impacts and those that do not. In contrast to the CX at issue in *Bosworth,* DOE's CX has been drafted with the requisite specificity, given the nature of action to which it will apply. Furthermore, DOE has determined that the transport of natural gas by marine vessels adhering to applicable maritime safety regulations and established shipping methods and safety standards normally does not pose the potential for significant environmental impacts. Impacts beyond marine transport are beyond the scope of DOE's NEPA review.

In *Bosworth,* the court agreed with previous cases finding that the promulgation of agency NEPA procedures, including the establishment of new CXs, did not itself require preparation of an EA or EIS, but that agencies need only comply with CEQ regulations setting forth procedural requirements, including consultation with CEQ, and **Federal Register** publication for public comment. The court, however, found that the record relied on by the U.S. Forest Service to develop and justify a CX was deficient. Unlike the circumstances in *Bosworth,* DOE's proposed CX would not include exports with materially different environmental impacts. Although DOE's CX would apply to various types of natural gas exports, the degree of potential environmental effects are not expected to vary significantly based on the type or volume of natural gas to be exported, to the extent they comport with established applicable maritime safety regulations and shipping methods and safety standards. This is due, in part, to the safety controls imposed on vessels permitted to carry natural gas products.

Other commenters argued that DOE does not meet the standard for establishing a CX because it fails to take into account the potential environmental impacts of natural gas export beyond marine transit, noting that DOE has previously acknowledged other potential impacts associated with its export authorizations, including inducement of upstream natural gas production. However, DOE has not previously included potential upstream and downstream impacts as part of its NEPA analyses for natural gas export approvals.[31] Induced upstream production impacts are not reasonably foreseeable for NEPA purposes,[32] and are therefore not ''effects'' subject to analysis under NEPA.[33] Furthermore, downstream emissions at the point of consumption are too attenuated to be reasonably foreseeable and do not have a reasonably close causal relationship to the granting of an export authorization. The Notice of Proposed Rulemaking and final rule are consistent with these principles.

One commenter noted that while DOE has relied on the life cycle analyses (LCAs) to support its public interest determination, the subject matter falls outside DOE's NEPA review obligations because the regasification and ultimate burning of LNG in foreign countries are beyond the scope of DOE requirements under NEPA. DOE agrees with this comment.

IV. Compliance With Applicable NEPA Requirements

Some commenters raised concerns regarding the application of the proposed CX, arguing that the CX is invalid because it improperly excludes the consideration of end use impacts, including those related to climate change. Conversely, one commenter requested that DOE explain in the final rulemaking that effects should not be considered significant if they are remote in time, geographically remote, or the result of a lengthy causal chain. The commenter indicated that DOE should also state that for any required analysis of effects, ''a 'but for' causal relationship is insufficient to make an agency responsible for a particular effect under NEPA.'' [34] In response, DOE reiterates that the relationship between DOE's authorization decision and potential end use impacts is too attenuated to define end use impacts as reasonably foreseeable effects requiring NEPA review.

Additionally, commenters alleged that DOE's commissioning of Energy Information Administration (EIA) analyses of export impacts on domestic energy markets, including the 2018 study ''Macroeconomic Outcomes of Market Determined Levels of U.S. LNG Exports,'' show that DOE considers the upstream impacts of its export decisions. The EIA studies informed DOE's public interest analysis under the NGA, but they do not analyze potential environmental impacts and have not been included as part of DOE's NEPA analyses supporting the natural gas export decision-making process.

Commenters stated that DOE could rely on the locations of interstate pipelines to develop a reasonable estimate of where increased upstream production of natural gas may occur as a result of an authorization of natural gas exports. DOE disagrees with this comment. The question of whether upstream production impacts should be

and FLNG Liquefaction, LLC, DOE/FE Order No. 3282, Order Conditionally Granting Long-Term Multi-Contract Authorization to Export Liquefied Natural Gas by Vessel From the Freeport LNG Terminal on Quintana Island, Texas, to Non-Free Trade Agreement Nations (May 17, 2013)) (''receiving a non-FTA authorization from DOE does not guarantee that a particular facility would be financed and built; nor does it guarantee that, even if built, market conditions would continue to favor export once the facility is operational.'').

[28] *Sierra Club* v *Bosworth,* 510 F.3d 1016 (9th Cir. 2007).

[29] U.S. Forest Service, FSH 1909.15, at 31.3 (May 28, 2014).

[30] 40 CFR 1501.9.

[31] *See* Texas LNG Brownsville LLC, DOE/FE Order No. 4489, FE Docket No. 15–62–LNG, Opinion and Order Granting Long-Term Authorization to Export Liquefied Natural Gas to Non-Free Trade Agreement Nations, at 40–42 (Feb. 10, 2020) (reviewing the content of the life cycle analyses (LCAs) and Addendum; noting that the information in the LCA is too general to play a direct role in the NGA public interest analysis, and explaining that the Addendum supports the public interest analysis, but that environmental concerns should be addressed directly through environmental regulation, and that ''section 3(a) of the NGA is too blunt an instrument to address these environmental concerns efficiently.'').

[32] *Sierra Club* v. *U.S. Dep't of Energy,* 867 F.3d 198 (''The Department offered a reasoned explanation as to why it believed the indirect effects pertaining to increased gas production were not reasonably foreseeable.'').

[33] 40 CFR 1508.1(g).

[34] *Quechan Indian Tribe of the Fort Yuma Indian Reservation* v. *U.S. Dept. of the Interior,* 547 F. Supp. 2d 1033, 1042 (D. Ariz. 2008) (citing *Public Citizen,* 541 U.S. 767).

included in the scope of DOE's NEPA analyses has been addressed by the D.C. Circuit. The D.C. Circuit has held that DOE has provided ''a reasoned explanation as to why it believe(s) the indirect effects pertaining to increased gas production were not reasonably foreseeable'' and therefore not subject to NEPA review.[35] The court found that ''(b)ecause the Department could not estimate the locale of production, it was in no position to conduct an environmental analysis of corresponding local-level impacts, which inevitably would be more misleading than informative.'' [36] The current CEQ NEPA regulations confirm that effects must be ''reasonably foreseeable and have a reasonably close causal relationship to the proposed action'' to be considered under NEPA, and note that ''effects should generally not be considered if they are remote in time, geographically remote, or the product of a lengthy causal chain.'' [37] Under this standard, consideration of upstream impacts is not required.

Commenters suggested that DOE prepare a programmatic environmental impact statement to streamline NEPA review of natural gas export authorizations. DOE has identified no information to indicate that natural gas export authorizations pose the potential for significant environmental impacts.[38] Therefore, a CX is the appropriate level of NEPA review, and preparation of a programmatic environmental impact statement is not required, nor is it necessary.[39]

Other commenters suggested that DOE should continue to evaluate NGA Section 3 export authorizations on a case-by-case basis to determine whether an EA or EIS is appropriate. As described in the section of this final rule titled ''How does DOE make a CX determination?,'' the proposed CX would be applied on a case-by-case basis. For any request for export authorization, DOE would apply the CX only after determining that the subject authorization complies with 10 CFR 1021.410, including that it presents no extraordinary circumstances warranting preparation of an EA or EIS, and with the integral elements listed in appendix B of DOE's NEPA regulations.

Some commenters argued that DOE should be assessing the potential environmental impacts stemming from the construction or operation of natural gas export facilities. As noted in the ''Background'' section of this document, under Section 3 of the Natural Gas Act, DOE's authority is limited to reviewing applications for natural gas exports; FERC (or, in the case of a facility falling outside FERC jurisdiction, MARAD or BOEM) reviews applications to construct and operate natural gas import and export facilities. Because DOE lacks the authority to prevent effects stemming from the construction and operation of such a facility, it has appropriately focused its environmental review on proposals over which it has approval authority, as required by NEPA.

Finally, some commenters noted that CEQ was, at the time of the comment period on the Notice of Proposed Rulemaking, in the process of revising its NEPA regulations. These commenters stated that DOE must comply with the CEQ regulations in effect, rather than proposed revisions. DOE prepared the Notice of Proposed Rulemaking consistent with the CEQ regulations in effect at the time the Notice of Proposed Rulemaking was published. DOE has prepared this final rule in light of the current CEQ regulations, which became effective on September 14, 2020, and DOE has determined, in consultation with CEQ, that the rule is consistent with those regulations.

C. Comments Regarding DOE's Reading of Public Citizen

Certain commenters challenged DOE's reading of *Public Citizen* as overly broad, arguing that DOE is incorrect in its conclusion that the case permits DOE to focus exclusively on the marine transport related effects of its export authorizations. In DOE's view, *Public Citizen* held that an agency has no obligation to ''gather or consider environmental information if it has no statutory authority *to act on that information.*'' [40] This final rule is fully consistent with that holding.

D. Comments Regarding Indirect and Cumulative Impacts and Related DOE Authority

Some commenters suggested that by establishing a CX for exports of natural gas, DOE is evading the obligation to perform NEPA review. As identified in the CEQ and DOE NEPA regulations, a CX is a form of NEPA review, and DOE has complied with the requirements of NEPA by determining that this class of actions normally does not have a significant effect on the human environment.[41] Application of the revised CX B5.7 will occur on a case-by-case basis as described in the section of this final rule titled ''How does DOE make a CX determination?'' As explained previously, DOE is tailoring its environmental review consistent with the court's holding in *Public Citizen.*

In further delineating agencies' NEPA review obligations, the D.C. Circuit in *Freeport II* agreed with DOE's rationale that effects pertaining to increased gas production were not reasonably foreseeable. Under this standard, DOE's analysis is properly limited to impacts stemming directly from decisions made pursuant to its statutory authority. The D.C. Circuit has held that local idiosyncrasies coupled with the limitations of estimating geology at the local level, and the uncertainty of predicting local regulation, land use patterns, and the development of supporting infrastructure are all local environmental issues presented by unconventional gas production. Accordingly, DOE's review of potential environmental impacts begins at the point of export, and is limited to the marine transport effects covered by the revised CX. The CX, which provides DOE with an option for full NEPA compliance, does not evade NEPA review.

E. Comments Regarding DOE's LCA

As discussed in the Notice of Proposed Rulemaking, this rulemaking is consistent with—but not dependent upon—two LCAs that DOE commissioned to calculate the life cycle greenhouse gas (GHG) emissions for LNG exported from the United States. DOE commissioned both the original LCA, published in 2014,[42] and an updated LCA, published in 2019,[43] to evaluate environmental aspects of LNG export applications under NGA section 3(a). Both LCAs concluded that the use of U.S. LNG exports for power production in European and Asian markets will not increase global GHG emissions from a life cycle perspective, when compared to regional coal extraction and consumption for power

[35] *Sierra Club* v. *U.S. Dep't of Energy,* 867 F.3d 198.

[36] *Id.* at 199 (internal citations omitted).

[37] 40 CFR 1508.1(g).

[38] *See* Technical Support Document.

[39] 40 CFR 1501.4.

[40] *Sierra Club* v. *Federal Energy Regulatory Comm'n,* 867 F.3d 1357, 1372 (D.C. Cir. 2017) (stating that rule was the touchstone of *Public Citizen*).

[41] 40 CFR 1508.1(d).

[42] U.S. Dep't of Energy, Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States, 79 FR 32260 (June 4, 2014) (LCA GHG Report).

[43] U.S. Dep't of Energy, Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States; Notice of Availability of Report Entitled Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States: 2019 Update and Request for Comments, 84 FR 49278 (Sept. 19, 2019) (LCA GHG Update).

production.[44] These reports are not part of DOE's NEPA review process, inasmuch as the regasification and ultimate combustion of regasified U.S. LNG in foreign countries are beyond the scope of appropriate NEPA review in this context.

Some commenters on the Notice of Proposed Rulemaking stated that the LCAs are deficient because they underestimate methane emissions associated with natural gas production and do not account for the rise of renewable energy in overseas markets. As noted, the LCA is not a NEPA document. Comments regarding its adequacy do not address DOE's NEPA analysis and related regulations, or the proposed changes in the Notice of Proposed Rulemaking.

Furthermore, comments stating that the LCAs are deficient parallel comments that DOE received on the 2019 LCA GHG update regarding methane emission estimates. DOE responded to those comments before finalizing the 2019 LCA GHG update.[45] Among other relevant points, DOE explained in its earlier response the basis for use of 0.7% as the average methane leakage rate in the LCA GHG update, how DOE's analysis considered the natural gas supply chain, differences in top-down and bottom-up methodologies, and how studies cited by commenters relate to DOE's analysis. DOE directs readers to that document for additional background information and discussion. Commenters on the Notice of Proposed Rulemaking have not raised information or arguments that were not raised and responded to in the 2019 GHG LCA update.

With regard to the second point—the rise of renewable energy in overseas markets—DOE also received and responded to similar comments on the 2019 LCA GHG update. DOE explained its use of coal-fired power as a comparative scenario to natural gas. DOE also explained limitations on expanding the analysis to include a broader array of fuel types and on modeling the effect that U.S. LNG exports would have on net global GHG emissions. Commenters also suggested that U.S. LNG exports would compete with renewable energy sources, while other commenters noted that natural gas-fueled power plants, because of their ability to power up quickly, may be used as a backup to renewable energy sources. DOE acknowledges these comments, but notes that these comments are beyond the reasonable scope of analysis for this rulemaking.

F. Comments Regarding DOE's Technical Support Document

Commenters stated that the Technical Support Document only considered one pathway for potential environmental impacts (leaks during natural gas transportation) and did not address potential impacts to wildlife during marine transport from noise and ship strikes, air pollutants and greenhouse gas emissions from the marine vessels, and impacts from invasive species that travel in ballast water. The Technical Support Document is focused on the potential impacts associated with transporting the LNG cargo. The Technical Support Document includes consideration of accidents (including spills and fires), safety and security during transport, and some 50 years of experience transporting LNG on marine vessels. With regard to comments related to potential environmental impacts of shipping generally, DOE's approval of export authorizations for natural gas has the potential to contribute only a very small amount to total shipping. More than 82,000 oceangoing vessels called at U.S. ports in 2015.[46] LNG shipments associated with DOE export authorizations numbered 209 in 2017, 330 in 2018, and 563 in 2019.[47] These LNG shipments comprise less than one percent of vessel calls from U.S. ports annually. Even with increased LNG exports, the relative proportion of LNG shipments to total shipping is not expected to change substantially. Thus, marine transport from DOE's actions does not have the potential to markedly affect the global environmental impacts associated with the commercial shipping industry.

Some commenters further stated that the Technical Support Document downplays significant spill and terrorism-related safety concerns. DOE's Technical Support Document includes a discussion of these concerns, as the commenters noted. The studies referenced in the Technical Support Document analyzed a number of scenarios, most involving fires, and provided information and recommendations to help manage and reduce hazards. Commenters pointed to a 2007 report[48] by the U.S. Government Accountability Office that identified additional areas for research into LNG spills and fires. That report resulted in recommendations that DOE accepted and incorporated into a study conducted by Sandia National Laboratories.[49] DOE's technical studies and related research by others to examine the hazards of potential fires and the consequences of malevolent acts is part of the process used by regulatory agencies and industry to understand and mitigate risks.

Commenters suggested that DOE cannot rely on certifications and requirements from other Federal agencies (*e.g.,* FERC, the Department of Transportation, and the Department of Homeland Security) and that doing so in the Technical Support Document amounted to a refusal to look at the potential environmental impacts associated with transportation of LNG by marine vessel. DOE notes that it is common practice to consider regulatory requirements (in this case, requirements intended to minimize any environmental impacts of marine transport of LNG), as well as analyses and determinations by other Federal agencies and external parties, in determining the potential impacts of the activity that is the focus of an agency's NEPA review. Also, DOE did not rely in the Technical Support Document only on the safety aspects of existing regulations. Rather, the effectiveness of those regulations and industry practices over decades of LNG transport provide strong evidence that there is normally no potential for significant environmental impacts due to marine transport of LNG.

G. Comments Regarding Review by the Federal Energy Regulatory Commission

Some commenters discussed the nature of DOE's interaction with FERC when approving natural gas exports. One commenter stated that DOE must actively participate in FERC's environmental review process. DOE intends to continue to participate as a cooperating agency in FERC's environmental review of natural gas export facilities.

Several commenters noted that DOE's proposed revision reflects an appropriate approach to balancing FERC

[44] *See, e.g.,* U.S. Dep't of Energy, Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States: 2019 Update—Response to Comments, 85 FR 72 78, 85 (Jan. 2, 2020).

[45] U.S. Dep't of Energy, Life Cycle Greenhouse Gas Perspective on Exporting Liquefied Natural Gas From the United States: 2019 Update—Response to Comments, 85 FR 72 (Jan. 2, 2020).

[46] Bureau of Transp. Stat., U.S. Dep't of Transp., Freight Facts and Figures 2017, *https://rosap.ntl.bts.gov/view/dot/34923.*

[47] Office of Fossil Energy, U.S. Dep't of Energy, LNG Monthly 2020, *https://www.energy.gov/fe/downloads/lng-monthly-2020.*

[48] U.S. Gov't Accountability Office, Maritime Security: Public Safety Consequences of a Terrorist Attack on a Tanker Carrying Liquefied Natural Gas Need Clarification, GAO-07–316 (Feb. 2007), *https://www.gao.gov/new.items/d07316.pdf.*

[49] U.S. Dep't of Energy, Liquefied Natural Gas Safety Research: Report to Congress, (May 2012), *https://www.energy.gov/fe/downloads/lng-safety-research-report-congress.*

and DOE's respective responsibilities. They explain that the proposed revisions do not impede FERC's ability to carry out its responsibilities and do not reflect an intention to hinder environmental review of facilities subject to section 3 of the NGA. One commenter noted that DOE's jurisdiction rests solely with the export of natural gas, and that DOE lacks the authority to approve the construction or operation of the natural gas facility itself, which rests with FERC. The commenter stated that because DOE lacks authority over construction and operation, it need not review potential environmental impacts associated with the facilities themselves. Instead, the commenter maintained that under *Public Citizen,* DOE should limit its review to the potential environmental impacts within DOE's authority, namely the impacts that occur at or after the point of export. DOE acknowledges these comments and has revised its NEPA regulations consistent with the view expressed in the comments.

Commenters suggested that there will be a regulatory gap when an export facility does not fall within FERC jurisdiction. DOE lacks the statutory authority to authorize construction and operation of export facilities, regardless of whether these facilities are deemed jurisdictional by FERC. Therefore, DOE need not review environmental impacts associated with those authorizations. For a proposed export facility outside FERC jurisdiction, another Federal agency, such as MARAD or BOEM, would typically be responsible for completing the NEPA review.

III. Procedural Requirements

A. Review Under Executive Order 12866

This final rule has been determined not to be a significant regulatory action under E.O. 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB).

B. Review Under National Environmental Policy Act

The Department's NEPA procedures assist the Department in fulfilling its responsibilities under NEPA and the CEQ regulations, but are not themselves final determinations of the level of environmental review required for particular proposed actions. The CEQ regulations do not direct agencies to prepare an EA or EIS before establishing agency procedures that supplement the CEQ regulations to implement NEPA (40 CFR 1507.3). *See Heartwood, Inc.* v. *U.S. Forest Service,* 73 F. Supp. 2d 962, 972–73 (S.D. III. 1999), aff'd, 230 F.3d 947, 954–55 (7th Cir. 2000). In establishing this CX, DOE is following the requirements of CEQ's procedural regulations, which include publishing the Notice of Proposed Rulemaking in the **Federal Register** for public review and comment, considering public comments, and consulting with CEQ to obtain CEQ's written determination of conformity with NEPA and the CEQ regulations. (*See* 40 CFR 1507.3(b)(2)).

Furthermore, DOE notes that this rulemaking is also categorically excluded under DOE's NEPA regulations (A6, Procedural rulemakings). In any case, the Department does not anticipate any significant environmental impacts from this final rule, and there are no extraordinary circumstances present.

C. Review Under Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of a final regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by E.O. 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process (68 FR 7990). DOE has made its procedures and policies available on the Office of the General Counsel's website: *https://energy.gov/gc.*

DOE has reviewed this final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. This final rule does not directly regulate small entities. The revisions to 10 CFR part 1021 revise the scope of CX B5.7 by removing reference to operation of natural gas facilities and adding ''transportation of natural gas by marine vessel.'' The revisions also focus on the export of natural gas because imports are deemed by law to be in the public interest. The revisions are intended to appropriately focus DOE's NEPA analysis for natural gas export applications, and do not impose any new requirements on small entities. DOE anticipates that the rule could reduce the burden on applicants for conducting environmental reviews.

On the basis of the foregoing, DOE certified that the proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. DOE's certification and supporting statement of factual basis was provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b). DOE received no comments on its certification or any potential economic impact of the proposed rule, and did not make changes in this final rule to the rule as proposed.

D. Review Under Paperwork Reduction Act

This rulemaking will impose no new information or record-keeping requirements. Accordingly, OMB clearance is not required under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

E. Review Under Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) generally requires Federal agencies to examine closely the impacts of regulatory actions on state, local, and tribal governments. Subsection 101(5) of title I of that law defines a Federal intergovernmental mandate to include any regulation that would impose upon state, local, or tribal governments an enforceable duty, except a condition of Federal assistance or a duty arising from participating in a voluntary Federal program. Title II of that law requires each Federal agency to assess the effects of Federal regulatory actions on state, local, and tribal governments, in the aggregate, or to the private sector, other than to the extent such actions merely incorporate requirements specifically set forth in a statute. Section 202 of that title requires a Federal agency to perform a detailed assessment of the anticipated costs and benefits of any rule that includes a Federal mandate which may result in costs to state, local, or tribal governments, or to the private sector, of $100 million or more in any one year (adjusted annually for inflation) (2 U.S.C. 1532(a) and (b)). Section 204 of that title requires each agency that proposes a rule containing a significant Federal intergovernmental mandate to develop an effective process for obtaining meaningful and timely input from elected officers of state, local, and tribal governments (2 U.S.C. 1534).

This final rule amends DOE's existing regulations governing compliance with NEPA to update DOE's regulations for the reasons described in Section I. Background, of this document. This

final rule will not result in the expenditure by state, local, and tribal governments in the aggregate, or by the private sector, of $100 million or more in any one year. Accordingly, no assessment or analysis is required under the Unfunded Mandates Reform Act of 1995.

F. Review Under Treasury and General Government Appropriations Act, 1999

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

G. Review Under Executive Order 13132

E.O. 13132, ''Federalism,'' 64 FR 43255 (Aug. 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt state law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the states and carefully assess the necessity for such actions. DOE has examined this final rule and has determined that it will not preempt state law and will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. No further action is required by E.O. 13132.

H. Review Under Executive Order 12988

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

I. Review Under Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB.

OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

J. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1)(i) Is a significant regulatory action under E.O. 12866, or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action would not have a significant adverse effect on the supply, distribution, or use of energy, nor was it determined to be a significant energy action by the OIRA Administrator, and it is therefore not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

K. Review Under Executive Order 12630

DOE has determined pursuant to E.O. 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (Mar. 18, 1988), that this final rule would not result in any takings that might require compensation under the Fifth Amendment to the United States Constitution.

L. Review Under Executive Orders 13771 and 13777

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

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

(i) Eliminate jobs, or inhibit job creation;

(ii) Are outdated, unnecessary, or ineffective;

(iii) Impose costs that exceed benefits;

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

(v) Are inconsistent with the requirements of Information Quality Act, or the guidance issued pursuant to that Act, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are

insufficiently transparent to meet the standard for reproducibility; or

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

DOE concludes that this rulemaking is consistent with the directives set forth in these Executive Orders. This final rule will update and improve efficiency in DOE's implementation of NEPA by appropriately focusing DOE's NEPA analysis for natural gas export applications and eliminating certain requirements of its existing regulations that are unnecessary.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding the issuance of this final rule prior to the effective date set forth at the outset of this rulemaking. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 801(2).

Approval of the Office of the Secretary

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

List of Subjects in 10 CFR Part 1021

Environmental impact statements.

Signing Authority

This document of the Department of Energy was signed on November 24, 2020, by William S. Cooper III, General Counsel, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 25, 2020.

Treena V. Garrett,

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

For the reasons stated in the preamble, DOE amends part 1021 of Chapter X of Title 10 of the Code of Federal Regulations as set forth below:

PART 1021—NATIONAL ENVIRONMENTAL POLICY ACT IMPLEMENTING PROCEDURES

■ 1. The authority citation for part 1021 continues to read as follows:

Authority: 42 U.S.C. 7101 *et seq.;* 42 U.S.C. 4321 *et seq.;* 50 U.S.C. 2401 *et seq.*

■ 2. Appendix B to subpart D of part 1021 is amended by:

■ a. Revising section B5.7; and

■ b. Removing and reserving section B5.8.

The revision reads as follows:

Appendix B to Subpart D of Part 1021—Categorical Exclusions Applicable to Specific Agency Actions

* * * * *

B5. * * *

* * * * *

B5.7 Export of natural gas and associated transportation by marine vessel

Approvals or disapprovals of new authorizations or amendments of existing authorizations to export natural gas under section 3 of the Natural Gas Act and any associated transportation of natural gas by marine vessel.

B5.8 [Removed and Reserved]

* * * * *

Appendix C to Subpart D of Part 1021—Classes of Actions That Normally Require EAs But Not Necessarily EISs

C13 [Removed and Reserved]

■ 3. Remove and reserve section C13.

Appendix D to Subpart D of Part 1021—Classes of Actions That Normally Require EISs

D8 and D9 [Removed and Reserved]

■ 4. Remove and reserve sections D8 and D9.

[FR Doc. 2020–26459 Filed 12–3–20; 8:45 am]

BILLING CODE 6450–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

RIN 3245–AH04

SBA Supervised Lenders Application Process

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: The U.S. Small Business Administration (SBA or Agency) is amending the regulations applicable to Small Business Lending Companies (SBLCs) and state-regulated lenders (Non-Federally Regulated Lenders (NFRLs) (collectively referred to as SBA Supervised Lenders). The key amendments to the regulations include a new application and review process for SBA Supervised Lenders, including for transactions involving a change of ownership or control. Other amendments to the regulations include updating the minimum capital maintenance requirements, clarifying the factors SBA will consider in its evaluation of an SBA Supervised Lender application and limiting the 7(a) lending area for NFRLs.

DATES: This rule is effective January 4, 2021.

FOR FURTHER INFORMATION CONTACT: Paul Kirwin, Chief, SBA Supervised Lender Oversight Team, Office of Credit Risk Management, Office of Capital Access, U.S. Small Business Administration, 409 3rd Street SW, Washington, DC 20416; telephone: (202) 205–7261; email: *paul.kirwin@sba.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information

The 7(a) Loan Program is a business loan program authorized by section 7(a) of the Small Business Act (15 U.S.C. 636(a)) and is governed primarily by the regulations in part 120 of title 13 of the Code of Federal Regulations (CFR). The core mission of the 7(a) Loan Program is to provide SBA-guaranteed financial assistance to small businesses that lack access to capital on reasonable terms and conditions to support our nation's economy.

Most Lenders participating in the 7(a) Loan Program are depository institutions that have a primary Federal Financial Institution Regulator (as defined in 13 CFR 120.10) that oversees the Lender's lending activities. SBA has statutory authority under section 7(a)(17) of the Small Business Act to authorize non-federally regulated entities to make 7(a) loans, including entities that have state regulators. Under this authority, SBA has authorized SBA Supervised Lenders to make loans in the 7(a) Loan Program. SBA Supervised Lenders are defined in 13 CFR 120.10 to include SBLCs and NFRLs, and are subject to regulation, oversight, and enforcement by SBA.

SBLCs are non-depository lending institutions that are authorized only to make loans pursuant to section 7(a) of the Small Business Act and loans to Intermediaries in SBA's Microloan program. SBLCs are regulated, supervised, and examined solely by SBA, except for the subset of SBLCs defined as Other Regulated SBLCs in 13 CFR 120.10. SBA imposed a moratorium on issuing additional SBA lending

authorities (referred to as SBLC Licenses) to SBLCs in 1982. Currently, there are fourteen (14) SBLCs with the authority to make 7(a) loans up to the maximum loan amount allowed under the Small Business Act.[1] An entity may purchase one of the fourteen (14) SBLC Licenses from an existing SBLC with SBA's prior written approval.

NFRLs are business concerns that are subject to regulation, supervision and oversight by a state regulator that must be satisfactory to SBA. By definition, an NFRL's lending activities are not regulated by a Federal Financial Institution Regulator. NFRLs are typically organized as state licensed Business and Industrial Development Companies (BIDCOs) and may include other types of state-regulated lending institutions, such as non-profit corporations or financial institutions without Federal deposit insurance or share insurance protection.[2]

To become an SBA Supervised Lender, an applicant must be qualified as determined by SBA in its sole discretion. An entity interested in becoming an SBA Supervised Lender must submit an application to SBA containing the information specified in SBA's Standard Operating Procedures 50 10, Lender and Development Company Loan Programs, as amended from time to time (SOP 50 10).[3]

On January 13, 2020, SBA published a proposed rule with a request for comments in the **Federal Register** to amend the regulations related to the SBA Supervised Lender application and review process and to mitigate certain risks inherent in their participation in the 7(a) Loan Program. 85 FR 1783 (January 13, 2020). The proposed changes were designed to: Improve efficiencies related to the SBA Supervised Lender application and review process, including for a change of ownership or control transaction (as defined in § 120.468); incorporate into the regulations the factors SBA will consider in its evaluation of an application; and mitigate the increased risk associated with the lending operations of SBA Supervised Lenders by updating their minimum capital maintenance requirements and establishing a 7(a) lending area for NFRLs.

II. Summary of Comments

SBA received 19 comments on the proposed rule. Seven comments were submitted by or on behalf of SBLCs. Three comments were submitted by or on behalf of NFRLs. Three comments were submitted by or on behalf of state regulators. SBA also received comments from two trade associations, two law firms, and two individuals.

The comments were generally supportive of the proposed application and review process with some suggested changes to shorten the waiting period for entities seeking to reapply to become an SBA Supervised Lender. Commenters generally agreed with SBA's proposed definition of qualified full-time professional management with minor changes. The commenters were also generally in favor of the changes to the minimum capital maintenance requirements with some proposed changes. A majority of the commenters were opposed to SBA limiting the 7(a) lending area for NFRLs to the state in which their primary state regulator is located. Commenters also requested some technical changes to the proposed regulation related to SBA's evaluation of applications and the requirements for change of ownership or control transactions. Finally, there were several responses to SBA's request for comments on whether SBA should modify the contribution that servicing rights assets may have on an SBA Supervised Lender's capital maintenance requirement.

SBA appreciates the comments received and has incorporated many of the suggested changes into the final rule. SBA has addressed the comments to the proposed regulatory changes within the section-by-section analysis below.

III. Section-by-Section Analysis of Comments and Changes

A. SBA Supervised Lenders

1. Section 120.460 What are SBA's additional requirements for SBA Supervised Lenders?

SBA proposed to add two new paragraphs to § 120.460. Proposed paragraph (c) required all SBA Supervised Lenders to employ qualified full-time professional management, as is currently required for SBLCs. This proposed regulation also clarified the meaning of full-time professional management to include, at a minimum, the employment of a chief executive officer or equivalent to manage daily operations, a chief credit/risk officer, and at least one other full-time employee qualified by training and experience to carry out the SBA Supervised Lender's business plan. In addition, proposed paragraph (c) included a requirement that an SBA Supervised Lender must sustain a sufficient level of 7(a) lending activity in its area of operation.

Overall commenters supported proposed § 120.460(c). A few commenters suggested that SBA should allow SBA Supervised Lenders to fulfill the full-time professional management requirement by using shared employees from affiliate organizations. One commenter suggested SBA should eliminate the requirement for a third full-time employee.

SBA recognizes that SBA Supervised Lenders may have different staffing levels depending on the size of their 7(a) loan portfolios. However, SBA maintains its policy position that SBA Supervised Lenders must have a minimum level of internal oversight to independently manage their 7(a) lending operations. SBA considered the comments received and has revised the rule to permit SBA Supervised Lenders to meet the qualified full-time professional management requirement by having two full-time senior officers (*i.e.,* CEO and CCO/CRO), and one part-time employee (which may be a shared employee of the lender's affiliates). Existing SBA Supervised Lenders will not be required to comply with this regulatory definition of qualified full-time professional management unless, after the effective date of this final rule, the SBA Supervised Lender makes or acquires any 7(a) loans or engages in a transaction that constitutes a change of ownership or control.

SBA received six comments in support of the requirement in paragraph

[1] SBA waived certain regulations for the purpose of permitting mission-oriented lenders to participate in SBA's Community Advantage Pilot Program (referred to as CA Lenders), a pilot program within the 7(a) Loan Program. Each CA Lender is identified as either an SBLC or NFRL, depending on whether the lender is subject to regulation by a state. CA Lenders are limited to making loans in the CA Pilot Program, which generally requires a CA Lender to make loans to underserved markets (*e.g.,* low-to-moderate income communities, rural areas, opportunity zones, veteran-owned businesses) and in an amount not to exceed $250,000. The CA Pilot Program is governed by all regulations applicable to the 7(a) Loan Program generally and to SBA Supervised Lenders specifically unless waived or modified in the **Federal Register** Notices published in connection with the CA Pilot Program. As indicated in the proposed rule, the revisions in this final rule do not apply to the CA Pilot Program. For more information about the CA Pilot Program please refer to the CA Participant Guide, Version 6.0 (June 15, 2020), available at *https://www.sba.gov/document/support-community-advantage-participant-guide.*

[2] This final rule does not apply to NFRLs authorized to make Paycheck Protection Program (PPP) loans under SBA Form 3507. For more information about PPP please refer to the information available on SBA's website at *https://www.sba.gov/funding-programs/loans/coronavirus-relief-options/paycheck-protection-program.*

[3] The current version of the SOP is 50 10 6, effective October 1, 2020. The application requirements can be found in this SOP in Part 1, Section A, Chapter 1, Paragraph A.2 with respect to NFRLs and Part 1, Section A, Chapter 2, Paragraph B with respect to SBLCs. The SOP is available at *https://www.sba.gov/document/sop-50-10-lender-development-company-loan-programs-0.*

(c) for each SBA Supervised Lender to maintain a sufficient level of lending activity in its area of operation. Most commenters requested that SBA clarify in the final rule the meaning of a ''sufficient'' level of lending activity. SBA considered these comments and has determined that a sufficient level of lending activity for SBA Supervised Lenders means obtaining at least four 7(a) loan approvals during two consecutive fiscal years. This is modeled on the minimum level of loan activity that SBA currently requires for Certified Development Companies in the 504 loan program. See 13 CFR 120.828. Existing SBA Supervised Lenders will not be required to comply with the 7(a) lending activity requirement unless, after the effective date of this final rule, the SBA Supervised Lender makes or acquires any 7(a) loans or engages in a transaction that constitutes a change of ownership or control.

Second, proposed new paragraph (d) limited an NFRL's 7(a) lending area to the state in which its primary state regulator is located. Overall, commenters were opposed to this part of the proposed rule. Some commenters argued that a limitation on the 7(a) lending area for NFRLs could have an impact on their business plans. Five commenters suggested that SBA should allow NFRLs previously engaged in nationwide 7(a) lending to continue such lending activities. One commenter supported the 7(a) lending area restriction for NFRLs, but suggested that SBA provide a 1-year transition period to allow NFRLs to adjust their future 7(a) lending activities.

As stated in the proposed rule, approximately 90 percent of all 7(a) loan approvals obtained by NFRLs during the last 3 fiscal years were for 7(a) loans to be made in the state where the NFRL's primary state regulator was located. Additionally, the final rule does not limit or restrict in any way an NFRL's ability to make other types of non-SBA loans to borrowers on a nationwide basis. While SBA understands that some state regulators may not object to nationwide 7(a) lending for NFRLs, state regulators do not bear the same financial risk that SBA assumes as the guarantor of 7(a) loans.[4] Moreover, while state regulators may generally oversee NFRLs within their borders for safety and soundness, SBA bears the responsibility of ensuring participating lenders comply with SBA Loan Program Requirements (as defined in 13 CFR 120.10). When SBA placed a moratorium on approving additional SBLCs in 1982, it did so to reduce the administrative resources needed to prudently regulate and oversee non-depository lenders with a nationwide 7(a) lending platform. SBA does not have the administrative resources needed to oversee NFRLs with a nationwide 7(a) lending platform in addition to the 14 SBLCs it currently regulates. In addition, proposed § 120.460(d) is consistent with state statutes placing geographic limits on lending activity overseen by state regulators, as well as a general understanding that NFRLs are expected to focus on economic development in their state and local communities.

SBA carefully considered the comments received on proposed § 120.460(d) and does not agree with the commenters' objections. In order to manage the Agency's limited administrative resources and the increased risk to SBA associated with NFRLs participating in the 7(a) Loan Program, the final rule establishes a 7(a) lending area for NFRLs limited to the state in which their primary state regulator is located. SBA will provide an exception such that an NFRL's lending area may include a local trade area that is contiguous to such state (*e.g.,* a city or metropolitan statistical area that is bisected by a state line) with SBA's prior written approval. SBA also is adopting a commenter's suggestion that NFRLs that are currently engaged in 7(a) lending outside of the state in which their primary regulator is located should not be subject to the 7(a) lending area limitation until 1 year after the effective date of the final rule. SBA will apply this rule immediately, however, to all new NFRLs and to any NFRL that engages in and/or is seeking approval of a change of ownership or control transaction. The 1-year grace period will allow the few NFRLs that may be affected by this rule to adjust their future 7(a) lending activities. SBA encourages existing or prospective NFRLs interested in making 7(a) loans on a nationwide basis to acquire one of the fourteen SBLC licenses that become available from time to time.

For further discussion of the impact of this provision, see the final regulatory flexibility analysis (FRFA) below.

2. Section 120.462 What are SBA's additional requirements on capital maintenance for SBA Supervised Lenders?

SBA proposed to amend the regulations to require NFRLs to maintain a baseline minimum amount of capital necessary for participation in the 7(a) Loan Program. The proposed rule established a minimum amount of capital equal to the higher of (1) the minimum amount of capital required by the NFRL's state regulator, or (2) $2,500,000. Commenters were generally supportive of the proposal. A few commenters indicated that the $2.5 million capital amount was too high, and SBA should instead allow the minimum capital requirement to be based on the size of the NFRL's loan portfolio. Other commenters suggested that the $2.5 million capital amount was too low and encouraged SBA to raise the minimum capital requirement for NFRLs to be at the same level as SBLCs (*i.e.,* $5 million).

SBA must ensure that NFRLs have a minimum level of capital necessary to manage the credit risk associated with their 7(a) lending operations. SBA disagrees with the comments suggesting that the amount should be increased or decreased and is moving forward with the rule as proposed. As SBA proposed, NFRLs will have 3 years after the effective date of this final rule to reach the new minimum capital amount. In addition, an NFRL that does not meet the new minimum capital requirement by the end of the 3-year period may remain in the 7(a) Loan Program but will not be permitted to make or acquire 7(a) loans after such date until it satisfies the minimum capital requirement. The minimum capital requirement will also apply immediately to new NFRLs and in the event of a change of ownership or control of an NFRL occurring and/or approved after the effective date of this final rule.

3. Section 120.466 SBA Supervised Lender Application

SBA proposed to add a new § 120.466 to codify a new application and review process for entities seeking to become an SBA Supervised Lender. SBA proposed to evaluate applications through an initial review and, if warranted, a final review.

The initial review requires an SBA Supervised Lender applicant to submit a written plan (known as a Lender Assessment Plan (LAP)). The LAP contains key information that would enable SBA to reach a preliminary assessment about the qualifications of an applicant expeditiously. An LAP review includes an initial assessment of the applicant's business plan, capitalization, and professional management team. SBA could also require an interview with the Office of Capital Access. If SBA were to notify an applicant that it may not proceed to the final review phase, the proposed rule

[4] SBA's guaranty on regular 7(a) loans ranges from 50% to 90% of the loan amount. Under the PPP, SBA's guaranty is 100% of the loan amount.

provided that the applicant must wait nine months from the date of such notification before reapplying by submitting a new LAP.

Overall commenters were supportive of the proposed rule. SBA received six comments suggesting the 9-month waiting period was too long and should be shortened to 3 months. SBA considered these comments and has agreed to shorten the waiting period from 9 months to 6 months to address the commenters' concerns. SBA believes that 3 months is too short a period to allow an applicant to make meaningful improvements in its circumstances.

The final review, as proposed under § 120.466(b), requires an SBA Supervised Lender applicant to submit a complete application to SBA. The complete application updates the information disclosed in the LAP and provides SBA with additional information for review, such as the applicant's organizational documents, operational plan, credit policies, internal control policies, loan risk rating system, capital adequacy plan, proposed credit facilities (if any), organizational chart, audited financial statements, bank statements, legal opinions and any other necessary documentation as further described in official SBA policies and procedures.[5] After completion of the final review, SBA issues a final decision to approve or deny the application. If an SBA Supervised Lender's application is denied, the proposed rule required an applicant to wait 18 months before it may submit a new LAP and restart the application process. The Agency received a number of comments requesting that SBA shorten this 18-month time period. SBA considered these comments and has agreed to shorten the time period from 18 months to 12 months. SBA believes a 1 year waiting period will allow the applicant to address material deficiencies and for meaningful and sustained improvement in its application.

Lastly, under proposed § 120.466(c), an entity seeking to become an NFRL is required to have at least one year of current operating and relevant commercial lending experience (by the entity itself) before the entity may submit an application to become an SBA Supervised Lender. SBA did not receive comments on this portion of the proposed rule and will include paragraph (c) in the final rule, with the clarification that it is the applicant that must have the requisite experience.

[5] The information required to be submitted in a complete application is not set forth in SBA's regulation but will continue to be in SBA's official policies and procedures. See SOP 50 10.

4. Section 120.467 Evaluation of SBA Supervised Lender Applicants

SBA proposed to add a new § 120.467 to incorporate into the regulations the factors SBA will consider in evaluating an SBA Supervised Lender applicant. SBA's evaluation will include a review of, among other things, the applicant's business plan, capitalization, operational plan, organizational structure, management qualifications, the historical performance of the loans originated by the applicant or attributable to its management team, the applicant's financial projections and liquidity, and prior history or involvement of the applicant or its management team (including key employees) with any SBA guaranteed lending program or any other Federal or state lending program. SBA also reviews the results of background investigations (*e.g.,* through SBA Form 1081) and other information obtained through due diligence and reference checks. Under the proposed rule SBA may also prohibit individuals or entities from participating as an officer, director, manager, owner or key employee of an SBA Supervised Lender applicant.

Commenters were generally in support of the proposed rule. SBA received four comments to proposed paragraph (b)(1) suggesting that it be revised to reflect that the individuals or entities that SBA may prohibit from serving as an officer, director, manager, owner or key employee of an SBA Supervised Lender are those that have ''materially'' failed to comply with SBA Loan Program Requirements. SBA has agreed to revise § 120.467(b)(1) by adding ''materially'' to this paragraph in the final rule.

5. Section 120.468 Change of Ownership or Control Requirements for SBA Supervised Lenders

SBA proposed to move the regulation applicable to a change of ownership or control of an SBLC (§ 120.475) to a new § 120.468 with certain modifications. The purpose of this change is to incorporate into the regulations the Agency's current policy requirement and practice that all SBA Supervised Lenders, including NFRLs, must obtain SBA written approval prior to any change of ownership or control.

Section 120.468(a) in the proposed rule clarified that SBA Supervised Lenders must receive SBA prior written approval before entering into a definitive agreement regarding a change of ownership or control. SBA received approximately 11 comments on this proposed rule. The commenters were opposed to the requirement to obtain SBA prior written approval before entering into a definitive agreement for a change of ownership or control. Most commenters requested that SBA either strike this provision from the rule or require a change of ownership or control to be ''conditioned'' upon receipt of SBA approval.

SBA disagrees with these comments. SBA is seeking to eliminate the time and expense associated with SBA Supervised Lenders entering into agreements for a change of ownership or control only to have SBA deny their requests months later after conducting a thorough review of the applications. Allowing SBA Supervised Lenders to enter into an agreement upfront (without prior SBA approval) would cause unnecessary time and expense to be expended by the parties in some cases and could unfairly raise expectations. The final rule retains the requirement that any SBA Supervised Lenders seeking to continue in the 7(a) Loan Program must obtain SBA's prior written approval before entering into an agreement for a change of ownership or control. To avoid confusion as to the meaning of a ''definitive'' agreement, SBA has removed the term and is clarifying that the limitation applies even if such agreement is conditioned on SBA approval. However, an SBA Supervised Lender may enter into a non-binding letter of intent regarding a prospective change of ownership or control, provided that such letter is reported to SBA within 30 calendar days. SBA removed the cross reference to § 120.464(a)(5) in the final rule in response to comments received.

Section 120.468(b) of the proposed rule clarified that if the approval of any state or Federal authority is required for an SBA Supervised Lender's change of ownership or control, such approval is required in addition to SBA's prior written approval. SBA did not receive any comments on this part of the proposed rule and will adopt the text in the final rule as proposed.

Section 120.468(c) of the proposed rule incorporated SBA's current policy that a new application must be submitted to SBA in connection with a change of ownership or control of an SBA Supervised Lender. SBA did not receive any comments on this part of the proposed rule and will adopt the text in the final rule as proposed.

Section 120.468(d) of the proposed rule provided that SBA Supervised Lenders would have an opportunity to voluntarily surrender their SBA lending authority (*i.e.,* the SBLC License or the NFRL lending authority) and withdraw from the 7(a) Loan Program with SBA's prior written approval. As proposed, a

voluntary surrender requires an SBA Supervised Lender to (i) transfer its entire loan portfolio to one or more Lenders acceptable to SBA, and (ii) enter into a withdrawal agreement. One commenter suggested that if a transferee for an SBA Supervised Lender's 7(a) loan portfolio could not be found, the final rule should be clarified so that SBA may take over the servicing of the SBA Supervised Lender's 7(a) loan portfolio. SBA agrees with this comment and has revised the final rule such that SBA may, in its sole discretion, elect to take over the servicing of an SBA Supervised Lender's 7(a) loan portfolio upon the voluntary surrender of its SBA lending authority. If SBA elects to take over servicing, the SBA Lender must assign the 7(a) loan documents to SBA and provide any needed assistance to allow SBA to take over servicing. SBA may use contractors to perform these actions. See 13 CFR 120.535(d).

6. Section 120.471 What are the minimum capital requirements for SBLCs?

SBA proposed to amend § 120.471(a) to increase the minimum capital requirement for SBLCs. As stated in the proposed rule, the minimum capital amount for SBLCs has not been updated since 1996. SBA believes the current minimum capital (of at least $1,000,000) is insufficient to assure an SBLC's continued financial viability or to provide for any necessary growth. As stated in the proposed rule, the maximum 7(a) loan amount has increased from $1,000,000 in 1996 to $5,000,000 as of the date of the proposed rule.[6] As a result, SBA has determined that a corresponding change to increase the minimum capital requirements for SBLCs is necessary at this time.

Under the proposed rule, SBLCs must maintain a minimum amount of capital equal to unencumbered paid-in capital and paid-in surplus of at least $5 million, or 10 percent of the aggregate of the SBLC's share of all outstanding loans, whichever is greater. Most of the 14 SBLCs have capital in excess of the minimum capital proposed under § 120.471(a). SBA also included a provision in the proposed rule providing SBLCs with 3 years after the effective date of the final rule to reach the new minimum capital amount. However, the proposed minimum capital amount would apply immediately in the event of a change of ownership or control of an SBLC occurring and/or approved after the effective date of this final rule.

Five commenters supported the proposed rule and two commenters were opposed. Commenters also encouraged SBA to modify the definition of regulatory capital so that SBA Supervised Lenders would not need to maintain capital against the full amount of the unguaranteed portion of 7(a) loans sold into securitizations. Three commenters also expressed some concerns about the proposed increase in capital for non-profit SBLCs and suggested that these entities should be permitted to use ''restricted'' capital toward their minimum capital requirement.

SBA considered the comments and is moving forward with the proposed rule as drafted. SBA disagrees that SBLCs should only be required to maintain capital against the risk retention portion of their 7(a) loan securitizations as opposed to the full amount of the unguaranteed portion of 7(a) loans sold into securitizations. SBA requires non-depository institutions (including SBA Supervised Lenders) that engage in securitization transactions to maintain capital in accordance with § 120.425(a). This regulation applies a capital charge against all assets of the securitizer including the balance outstanding on the unguaranteed portion of the securitizer's 7(a) loans, as well as including those unguaranteed interests in any securitization pool. SBA did not propose any revisions to § 120.425(a) in the proposed rule.

SBA also does not agree with the suggestion that non-profit SBLCs should be permitted to include ''restricted'' capital in their minimum capital calculation. An SBLC's capital must be ''unencumbered'' and available to absorb potential losses from its lending activities, including those associated with its entire 7(a) loan portfolio. Restricted capital does not meet this requirement. SBA will not permit non-profit SBLCs to include restricted capital towards their minimum capital calculation.

Finally, SBA will continue to study whether changes to the definition of capital under § 120.471(b) should be modified to account for the valuation of servicing rights assets. Most of the comments received suggested that SBA should allow SBLCs to receive full credit for the value of their servicing rights towards their minimum capital requirement. If SBA determines there is a need for further changes, SBA will promulgate regulations or provide additional guidance on this issue.

B. Technical Changes

1. Section 120.410 Requirements for All Participating Lenders

SBA proposed a conforming technical change to § 120.410(a)(1) to reflect the new minimum capital requirements for SBA Supervised Lenders. SBA did not receive any comments on this proposed technical change and incorporated the proposed text into the final rule.

2. Section 120.470 What are SBA's additional requirements for SBLCs?

SBA proposed a conforming technical change to remove § 120.470(g) ''Management'' and redesignate paragraph (h) as paragraph (g). No comments were received, and SBA is adopting the change in this final rule. The management requirement for SBLCs is addressed in new § 120.460(c).

3. Section 120.475 Change of Ownership or Control

SBA proposed a conforming technical change to remove and reserve § 120.475. No comments were received, and SBA is adopting the change in this final rule. The text of § 120.475 is incorporated into § 120.468.

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

Executive Order 12866

This rule finalizes a proposed rule that the Office of Management and Budget (OMB) determined was not a ''significant'' regulatory action for the purposes of Executive Order 12866. OMB did not change the non-significant designation for this final rule, and therefore, SBA has not prepared a Regulatory Impact Analysis. This is not a major rule under the Congressional Review Act, 5 U.S.C. 801 *et seq.*

Executive Order 13563

This executive order supplements and reaffirms the principles and requirements in Executive Order 12866, including the requirement to provide the public with an opportunity to participate in the regulatory process. SBA Supervised Lenders have been involved in the 7(a) Loan Program for over 35 years. Over the years, the Agency has received feedback from SBA Supervised Lender applicants and program participants, including valuable insight and suggestions for improvements to the application and review process. This feedback from SBA Supervised Lenders, together with the comments in response to the proposed rule, has shaped this final rule.

[6] In addition, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136), permits participating lenders to make section 7(a) loans up to a maximum amount of $10 million under the PPP.

Executive Order 13771

This final rule is not subject to Executive Order 13771 regulatory action because the rule is not significant under Executive Order 12866.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

SBA has determined that this final rule will not have substantial, direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. For the purposes of Executive Order 13132, SBA has determined that this rule has no federalism implications warranting preparation of a federalism assessment.

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

SBA has determined that this final rule imposes a new reporting requirement under the Paperwork Reduction Act (PRA). Specifically, the final rule requires SBA Supervised Lenders to submit a written Lender Assessment Plan (LAP) for SBA to conduct an initial review of the applicant. In addition, the final rule codifies a requirement for applicants to submit a complete application in order for SBA to determine whether the applicant has the qualifications necessary to participate in the 7(a) Loan Program as an SBA Supervised Lender. As discussed above, this requirement is currently described in SBA's official policies and procedures. In addition to these two requirements, the applicant will submit the same forms as other Lenders that apply to participate in the 7(a) Loan Program, including the SBA Form 1081, Statement of Personal History (OMB Control number 3245–0080).

The title, summary of the information collections, description of respondents, and an estimate of the related reporting burdens are discussed below. Additional information related to these requirements is included in the Regulatory Flexibility Act discussion in this rule. SBA did not receive comments on the new information collections in the proposed rule.

Title of Collection: SBA Supervised Lender Application and Review.

OMB Control Number: New Collection.

(a) Lender Assessment Plan.

The final rule requires organizations seeking to become an SBA Supervised Lender (or seeking SBA approval of a change of ownership or control) to submit a LAP to SBA. The LAP includes the legal name and contact information of the applicant, a written business plan, current and projected financial statements and other important information about the applicant and its management team (including key employees).

Need and Purpose: The LAP is necessary for SBA to conduct an initial review of an applicant seeking to become an SBA Supervised Lender (or seeking SBA approval of a change of ownership or control). The LAP provides SBA with key information that would enable SBA to reach a preliminary assessment about the qualifications of an applicant more efficiently. This initial review phase will assist SBA in identifying incomplete applications and unqualified applicants much earlier in the application review process.

Description and Estimated Number of Respondents: Pursuant to proposed § 120.466(a), the information in the LAP will be collected from each organization seeking to become an SBA Supervised Lender (or seeking SBA approval of a change of ownership or control). SBA estimates that it will likely receive no more than four LAPs each year.

Total Estimated Response Time: It is estimated that each applicant would need approximately 35 hours to prepare and submit the LAP for an estimated total of 140 hours annually.

(b) SBA Supervised Lender Application.

If an applicant seeking to become an SBA Supervised Lender (or seeking SBA approval of a change of ownership or control) is authorized by SBA to proceed to the final review phase, the applicant will be required to submit a complete application.

Need and Purpose: The information submitted with this application is necessary for SBA to reach a final decision regarding whether the applicant has the qualifications necessary to participate in the 7(a) Loan Program. The complete application requires an SBA Supervised Lender applicant to provide additional detail about the information previously disclosed to SBA in the LAP and will include new information about the applicant's proposed operation and lending activities as a participant in the 7(a) Loan Program. As stated above, these application requirements are not new since they are currently set out in SBA's official policies and procedures. Under those policies and procedures, an organization applying to become an SBA Supervised Lender (or seeking SBA approval of a change of ownership or control) is required to, among other things, submit documentation in support of its organizational structure, internal control policies, operational plan, proposed credit policies, loan risk rating system, proposed secondary market activities, capital adequacy plan, audited financial statements and other information (*e.g.,* certifications and legal opinions) necessary for SBA to evaluate the qualifications of the applicant. See SOP 50 10. Although SBA estimates that the requirements will only apply to approximately four organizations each year, now that SBA is codifying the application requirements in this final rule, under the PRA the requirements are deemed to impact ten or more respondents; therefore, SBA has also requested OMB approval of this application in compliance with the PRA procedures.

Description and Estimated Number of Respondents: The information in the complete application will be collected from organizations that are seeking to become an SBA Supervised Lender and have successfully reached the final review phase. Based on current experience, SBA estimates that it will likely receive no more than four complete applications each year.

Total Estimated Response Time: It is estimated that each applicant would need approximately 50 hours to prepare and submit a complete application, for an estimated total of 200 hours annually.

Regulatory Flexibility Act, 5 U.S.C. 601–612

Under the Regulatory Flexibility Act (RFA), this final rule may have an impact on a substantial number of small entities that participate as SBA Supervised Lenders in the 7(a) Loan Program. Immediately below, SBA sets forth a final regulatory flexibility analysis (FRFA) examining the impact of the final rule in accordance with 5 U.S.C. 603. The FRFA addresses (1) the reasons, objectives and legal basis for this rule; (2) a description of the kind and number of small entities that may be affected; (3) the projected reporting, recordkeeping and other compliance requirements; (4) whether there are any Federal rules that may duplicate, overlap, or conflict with this rule; and (5) whether there are any significant alternatives to this rule.

1. What are the reasons, objectives and legal basis for the rule?

The rule is designed to improve efficiencies and enhance the application and review process for organizations seeking to participate in the 7(a) Loan Program as SBA Supervised Lenders. The objective is to provide a process for a more efficient and effective evaluation of the qualifications of applicants seeking to become SBA Supervised Lenders. The new application and review process will provide greater clarity and transparency to applicants and would expedite SBA's review, which may potentially reduce costs on applicants and on SBA's limited administrative resources.

The rule also raises the minimum capital requirement that SBA Supervised Lenders must maintain to assure their continued financial viability and to provide for any necessary growth. The minimum capital requirement for SBA Supervised Lenders has not been updated by SBA for more than 23 years. The Agency has determined that the regulations addressing minimum capital must be amended to correspond with the more than 500 percent increase in the maximum 7(a) loan amount that Congress has authorized by statute over the last twenty-three years.

The rule also limits the 7(a) lending area for NFRLs to the state in which their primary regulator is located, except that an NFRL may request SBA's prior written approval to make 7(a) loans in a local trade area that is contiguous to such state (*e.g.,* a city or metropolitan statistical area that is bisected by a state line). Most NFRLs participating in the 7(a) Loan Program already limit their lending activities to the state in which their primary state regulator is located. In recent years, some state regulators have permitted NFRLs to make loans outside of their state or even nationwide. The expansion of an NFRL's 7(a) lending area increases risk to SBA and the Agency does not have the additional administrative resources to adequately supervise, regulate and examine NFRLs that operate outside of their state. This part of the final rule is also consistent with the general understanding that state-regulated lenders (such as BIDCOs) are licensed under specific state laws to focus primarily on economic development in their respective state and local communities. Based on the comments received, SBA has agreed to provide existing NFRLs that SBA has approved for 7(a) lending outside of the state in which their primary regulator is located with an additional one-year grace period to allow them to adjust their future 7(a) lending activities.

SBA is authorized to supervise the safety and soundness of SBA Supervised Lenders and may regulate their 7(a) lending activities pursuant to section 23(a) of the Small Business Act. 15 U.S.C. 650(a), see also 15 U.S.C. 634(b)(7). SBA has the authority to promulgate rules, regulations and requirements for the 7(a) Loan Program. 15 U.S.C. 634(b)(6).

2. What are SBA's description and estimate of the number of small entities to which the rule will apply?

SBA Supervised Lenders affected by this rule comprise a unique class of 36 non-depository lenders that may only participate in the 7(a) Loan Program and make 7(a) loans if authorized by SBA. This final rule will be applicable to all SBA Supervised Lenders (other than lenders participating as CA Lenders in the CA Pilot Program and lenders authorized to make PPP loans under SBA Form 3507). SBA estimates that approximately 88 percent of SBA Supervised Lenders are considered small entities based on NAICS sector code 52 (Finance and Insurance) and industry code 52298 (All Other Non-depository Credit Intermediation) and have annual receipts of less than $38.5 million. This estimate of 32 small SBA Supervised Lenders is based in part on information contained in the quarterly condition reports and the annual reports that are required to be submitted to SBA by such lenders.

3. What are the projected reporting, recordkeeping, and other compliance requirements of the rule and an estimate of the classes of small entities which will be subject to the requirements?

The final rule imposes a new reporting requirement for organizations seeking to become an SBA Supervised Lender (or seeking SBA approval of a change of ownership or control). The final rule codifies an existing requirement that applicants submit a complete application for SBA to determine whether an organization has the qualifications necessary to participate in the 7(a) Loan Program as an SBA Supervised Lender.

The LAP includes key information about an organization that will allow SBA to reach a preliminary assessment about the qualifications of an applicant more efficiently. SBA estimates it will receive approximately four LAPs each year. SBA estimates that it will take approximately 35 hours for an organization to prepare an LAP at a cost of $3,838 per LAP. Based on SBA's experience with similar data collections, we expect an organization that submits a LAP will need to employ the services of a financial manager and an administrative assistant when preparing an LAP for submission to SBA.[7]

If an organization is authorized by SBA to proceed to the final review phase, a complete application must be submitted to SBA. As mentioned above, the application requirements for SBA Supervised Lenders are not new and are currently set forth in SBA's official policies and procedures. See SOP 50 10 6, Part 1, Section A, Chapter 1, Paragraph A.2 for NFRLs and Part 1, Section A, Chapter 2, Paragraph B for SBLCs. SBA estimates that it will receive approximately four complete applications each year. SBA estimates that it will take approximately 50 hours for an organization to prepare a complete application at a cost of $5,207 per application. Based on SBA's experience with similar data collections, an organization applying to become an SBA Supervised Lender would typically employ the services of a financial manager, an accountant, an attorney and an administrative assistant when preparing a complete application for submission to SBA.[8] SBA did not receive comments on whether the number of hours estimated to prepare a complete application is appropriate or on the services they employ to complete the application.

SBA anticipates that there will be some costs for SBA Supervised Lenders related to the new minimum capital requirement under the rule. This rule establishes a new minimum capital requirement for SBLCs and NFRLs of at least $5 million and $2.5 million, respectively. Based on information provided to SBA by SBA Supervised Lenders in quarterly condition reports, 11 of the 14 SBLCs (*i.e.,* 79 percent) have at least $3.7 million in capital (and of those 11 SBLCs, 11 have more than $5 million in capital). In addition, 19 of the 22 NFRLs (*i.e.,* 86 percent) have more than $2.5 million in capital.

[7] The cost estimate for the LAP is based on hourly job position wages published by the U.S. Department of Labor's Bureau of Labor Statistics for 2019 and increased by 100% to account for benefits and overhead. The cost breakdown is as follows: Financial Manager (30 hours times an hourly rate of $124.90) plus Administrative Assistant (5 hours times an hourly rate of $36.24) equals $3,838.

[8] The cost estimate for a complete application is based on hourly job position wages published by the U.S. Department of Labor's Bureau of Labor Statistics for 2019 and increased by 100% to account for benefits and overhead. The cost breakdown is as follows: Financial Manager (30 hours times an hourly rate of $124.90) plus Accountant (10 hours times an hourly rate of $68.80) plus Attorney (5 hours times an hourly rate of $118.22) plus Administrative Assistant (5 hours times an hourly rate of $36.24) equals $5,207.

SBA has determined that there are seven small entities that will be impacted by the new capital requirements in the rule. In other words, 7 of the 36 SBA Supervised Lenders that are considered small entities will need to increase their capital to reach the new minimum capital requirement of either $2.5 million or $5 million (as applicable). SBA estimates the amount of capital that would need to be raised by these small entities currently ranges between $1,270,000 and $3,580,000. SBA estimates that this rule may have a significant economic impact on 6 of the 36 SBA Supervised Lenders (*i.e.,* 17 percent), each of which is considered a small entity. As noted above, all existing SBA Supervised Lenders will have 3 years from the effective date of a final rulemaking to comply with this part of the rule (other than for transactions involving a change of ownership or control of an SBA Supervised Lender).

SBA estimates that the cost of raising capital for SBA Supervised Lenders is approximately 9.8 percent of the amount of equity capital raised based on the Capital Asset Pricing Model (CAPM). The CAPM is one of the most widely used pricing models by financial professionals and considered the preferred method to estimate the cost of equity capital. See Duff & Phelps 2019 Valuation Handbook—U.S. Industry Cost of Capital (data through June 30, 2019).[9] SBA estimates that the total cost of raising new equity capital for the seven SBA Supervised Lenders based on the requirements of the rule would range in amount from approximately $124,000 to $350,000.[10] However, the cost is mitigated by the fact that under the rule SBA Supervised Lenders will have 3 years to increase their capital. Thus, the maximum amount that it would cost an existing SBA Supervised Lender to reach the new minimum capital requirement would be approximately $117,000 per year for 3 consecutive years.[11]

SBA determined that a 3-year time frame was a sufficient amount of time for SBA Supervised Lenders to increase their capital. SBA specifically requested comments on whether SBA Supervised Lenders should have 3 years to comply with the new minimum capital requirements under the proposed rule or should be required to comply sooner. The majority of the commenters were generally supportive of at least a 3-year time frame to meet the new minimum capital requirement.

The rule also limits the 7(a) lending area for NFRLs to the state in which their primary state regulator is located, except that with SBA approval it may include a local trade area that is contiguous to such state (such as a city or metropolitan statistical area bisected by a state line). There are currently 22 NFRLs participating in the 7(a) Loan Program. During the last 3 fiscal years, 2 NFRLs (each of which is considered a small entity) requested loan authorizations to make the majority of their 7(a) loans outside of the state in which their primary state regulator is located. Except for these two NFRLs, approximately 90 percent of the lending within the 7(a) Loan Program during the last 3 fiscal years was done in the state where the NFRL's primary state regulator is located. Approximately 79 percent of all 7(a) loan approvals obtained by NFRLs during the last 3 fiscal years were for loans to be made to small businesses located within their own state. This part of the rule will not impact a substantial number of small entities. It is important to note that this final rule will not impose any restrictions regarding an NFRL's non-7(a) lending activities. Therefore, the final rule will not have any impact on an NFRL's ability to generate business by making other types of non-SBA loans outside of its own state.

Most commenters did not support the limitation on 7(a) lending areas for NFRLs. SBA considered the comments received and has agreed to allow existing NFRLs one additional year to adjust to this portion of the rule. Therefore, NFRLs currently engaged in 7(a) lending outside of the state in which their primary regulator is located may continue to make 7(a) loans on a nationwide basis (if permitted by their primary state-regulator) for 1 year from the effective date of this final rule. This additional one-year grace period will not apply to new applications from NFRLs, including those that have engaged in and/or are seeking approval of a change of ownership or control.

In summary, SBA estimates that the total cost to a particular SBA Supervised Lender associated with this rule (including the costs related to data collection) will range from zero to $356,683, substantially all of which relates to the cost of raising capital and may be spread over a 3-year time period.

4. What are the relevant Federal rules which may duplicate, overlap, or conflict with the rule?

We are not aware of any Federal rules that duplicate, overlap or conflict with this rule. SBA's SOP 50 10 will have to be amended to conform to portions of this rule, which will be done separately.

5. What alternatives will allow the Agency to accomplish its regulatory objectives while minimizing the impact on small entities?

The Agency originally considered imposing the new minimum capital requirements for SBA Supervised Lenders immediately due to the risk associated with their lending operations. SBA recognized, however, that providing a 3-year period for SBA Supervised Lenders to increase their capital would be less burdensome on lenders and their operational plans. SBA took into consideration that some lenders may need time to plan their capital raising efforts and negotiate favorable terms and conditions for increasing their capital. The 3-year time period will provide SBA Supervised Lenders with a sufficient amount of time to raise new equity capital and an opportunity to increase capital by retaining earnings (which will reduce the estimated overall cost of raising such capital).

SBA believes many of the changes in this rule will benefit small entities interested in becoming an SBA Supervised Lender by clarifying areas in the application process where there was confusion and to make the process more transparent. This rule will also allow SBA to evaluate the qualifications of new applicants (including for change of ownership or control transactions) more efficiently and make well-informed decisions on SBA Supervised Lender applications. SBA believes this rule encompasses best practice guidance that aligns with the Agency's mission to increase access to capital for small businesses and facilitate American job preservation and creation.

List of Subjects in 13 CFR Part 120

Community development, Equal employment opportunity, Loan programs—business, Reporting and recordkeeping requirements, Small businesses.

[9] The 2019 Valuation Handbook—U.S. Industry Cost of Capital published by Duff & Phelps provides cost of capital estimates for approximately 170 industries identified by Standard Industrial Classification codes (SIC). For purposes of estimating the cost of raising equity capital for SBA Supervised Lenders, SBA used SIC code 61—non-depository credit institutions, which includes 21 companies that are engaged primarily in extending credit in the form of loans (but are not engaged in deposit banking). SBA compared the estimated cost of raising capital cited above with other sources and found the data to be similar.

[10] The estimated cost to raise $1.27 million or $3.58 million in equity capital would be as follows: $1,270,000 times 9.8% equals $124,000; $3.58 million times 9.8% equals $350,000.

[11] It should be noted that some existing SBA Supervised Lenders may decide to increase their capital by retaining earnings instead of raising new equity capital, which would reduce the cost of this rule.

For the reasons stated in the preamble, SBA is amending 13 CFR part 120 as follows:

PART 120—BUSINESS LOANS

■ 1. The authority for 13 CFR part 120 continues to read as follows:

Authority: 15 U.S.C. 634(b) (6), (b) (7), (b) (14), (h), and note, 636(a), (h) and (m), and note, 650, 657t, and note, 657u, and note, 687(f), 696(3) and (7), and note, and 697(a) and (e), and note.

§ 120.410 [Amended]

■ 2. Amend § 120.410 in paragraph (a)(1) by removing the phrase ''for SBLCs, meeting its SBA minimum capital requirement; and for NFRLs, meeting its state minimum capital requirement); and'', and adding in its place the phrase, ''and for SBLCs and NFRLs, meeting their respective minimum capital requirement); and''.

■ 3. Amend § 120.460 by adding paragraphs (c) and (d) to read as follows:

§ 120.460 What are SBA's additional requirements for SBA Supervised Lenders?

* * * * *

(c) An SBA Supervised Lender must have qualified full-time professional management including, but not limited to, a chief executive officer or the equivalent to manage daily operations, and a chief credit/risk officer. An SBA Supervised Lender must also have at least one other part-time professional employee (which may be a shared employee of the lender's affiliates) qualified by training and experience to carry out its business plan. An SBA Supervised Lender is expected to sustain a sufficient level of lending activity in its lending area, which means obtaining at least four 7(a) loan approvals during two consecutive fiscal years. This paragraph only applies to SBA Supervised Lenders that make or acquire a 7(a) loan after January 4, 2021, or to any SBA Supervised Lender approved after such date, including in the event of a change of ownership or control of an SBA Supervised Lender.

(d) An NFRL may only make or acquire 7(a) loans in the state in which its primary state regulator is located, except that an NFRL's lending area may include a local trade area that is contiguous to such state (*e.g.,* a city or metropolitan statistical area that is bisected by a state line) if the NFRL receives SBA's prior written approval. This paragraph applies to all NFRLs on or after January 4, 2021, including in the event of approval of a new NFRL or a change of ownership or control of an NFRL; provided however, that if SBA has approved any NFRL to make 7(a) loans out of their state, then this paragraph will apply on or after January 4, 2022.

■ 4. Amend § 120.462 by:

■ a. Removing the phrase ''by state regulators'' wherever it appears and adding in its place the phrase ''in § 120.462(a)(1)'';

■ b. Redesignating paragraphs (a) through (e) as paragraphs (b) through (f); and

■ c. Adding a new paragraph (a).

The addition reads as follows:

§ 120.462 What are SBA's additional requirements on capital maintenance for SBA Supervised Lenders?

(a) *Minimum capital requirements*—(1) *For NFRLs.* (i) Beginning on January 4, 2024, each NFRL that makes or acquires a 7(a) loan must maintain the minimum capital required by its state regulator, or $2,500,000, whichever is greater.

(ii) Any NFRL approved on or after January 4, 2021, including in the event of a change of ownership or control, must maintain the minimum capital requirement set forth in paragraph (a)(1)(i) of this section.

(iii) Unless subject to paragraph (a)(1)(i) or (ii) of this section, an NFRL must comply with the minimum capital requirements for NFRLs that were in effect on January 3, 2021.

(2) *For SBLCs.* For information on minimum capital requirements for SBLCs, see § 120.471.

* * * * *

■ 5. Add § 120.466 to read as follows:

§ 120.466 SBA Supervised Lender application.

An entity seeking to participate as an SBA Supervised Lender must apply to SBA. SBA evaluates SBA Supervised Lender applicants through an initial review and final review, as follows:

(a) *Initial review.* SBA Supervised Lender applicants must submit a written plan containing information about the organization and its current and proposed lending activities (''Lender Assessment Plan''). After SBA's review of the Lender Assessment Plan, the Office of Capital Access may require an interview with the applicant and its management team. SBA will determine, in its sole discretion, whether an applicant may proceed to the final review. If SBA determines that an applicant may not proceed to the final review, the applicant must wait at least 6 months before it may submit a new Lender Assessment Plan. Each applicant must demonstrate to SBA's satisfaction that it meets the ethical requirements and the participation criteria set forth in 13 CFR 120.140 and 120.410. The Lender Assessment Plan must include the following items:

(1) The legal name, address, telephone number and email address of the applicant;

(2) Business plan, detailing the applicant's proposed lending area and the volume of loan activity projected over the next 3 years (supported by current and projected balance sheets, income statements and statements of cash flows);

(3) Capitalization (current and proposed), including the form of organization and the identification of all debt and classes of equity capital and proposed funding amounts, including any rights or preferences accorded to such interests (*e.g.,* voting rights, redemption rights and rights of convertibility) and any conditions for the transfer, sale or assignment of such interests;

(4) A list of all members of the applicant's management team, including the applicant's officers, directors, managers and key employees, as well as the applicant's owners, Associates (as defined in § 120.10) and Affiliates (as defined in § 121.103 of this chapter);

(5) A written summary of the professional experience (including any prior experience with any SBA program) of the applicant's management team (including key employees);

(6) In connection with any application to become an SBLC, the applicant must include a letter agreement signed by an authorized official of an existing SBLC certifying that the SBLC is seeking to transfer its SBA lending authority to the applicant; and

(7) If approval of any state or Federal chartering, licensing or other regulatory authority is required, copies of any licenses issued by or documents filed with such authority.

(b) *Final review.* Each applicant that receives notice from SBA in writing that it may proceed to the final review must submit a complete application to SBA within 90 calendar days. The application requirements for SBA Supervised Lenders are set forth in official SBA policy and procedures. An incomplete application submitted to SBA will not be processed and will be returned to the applicant. SBA may, in its sole discretion, approve or deny any SBA Supervised Lender application. The decision to approve or deny an SBA Supervised Lender application is a final agency decision. If an SBA Supervised Lender application is denied by SBA or if a complete application is not timely submitted, the applicant may not submit a new Lender Assessment Plan and restart the application process until 12 months from the date of denial or the

date a complete application was due to SBA, as applicable.

(c) *NFRL operating and lending experience requirement.* For an entity seeking to become an NFRL, evidence of at least 1 year of current operating and relevant commercial lending experience by the entity must be provided.

■ 6. Add § 120.467 to read as follows:

§ 120.467 Evaluation of SBA Supervised Lender applicants.

(a) SBA will evaluate an SBA Supervised Lender applicant based on information from, among other sources, the Lender Assessment Plan, an interview with the applicant's management team (if required), the application and any other documentation submitted by the applicant, the results of background investigations, public record searches and due diligence conducted by SBA or other Federal or state agencies. SBA's evaluation will consider factors such as the following:

(1) Professional qualifications of its management team (including key employees), including demonstrated commercial lending experience, business reputation, adherence to legal and ethical standards, track record in making and monitoring business loans, and prior history, if any, working as an officer, manager, director or key employee of a lender involved in any SBA program or any other Federal or state lending program.

(2) Historical performance measures of loans originated by the applicant or attributable to its management team (including key employees), including loan default rates, purchase rates and loss rates, measured in both percentage terms and in comparison to appropriate industry benchmarks, review/examination assessments and other performance measures.

(3) The applicant's capitalization, organizational structure, business plan (including any risk factors), projected financial performance, financial strength, liquidity, the soundness of its financial projections and underlying assumptions, loan underwriting process, operations plan and the history of compliance of the applicant and its management team (including key employees) with SBA Loan Program Requirements.

(4) Whether the NFRL's state regulator and the state statute or regulations governing the NFRL's operations, including but not limited to those pertaining to audit, examination, supervision, enforcement and information sharing, are satisfactory to SBA in its sole discretion.

(5) For changes of ownership or control, in addition to the factors listed in paragraphs (a)(1) through (4) of this section, SBA will consider whether the applicant's plan for the resolution of any outstanding monetary liabilities to SBA, including repairs and denials and civil monetary penalties, is acceptable to SBA in its sole discretion.

(b) SBA may prohibit any individual or entity from participating as an officer, director, manager, owner or key employee of the applicant if such individual or entity:

(1) Has a previous record of failing to materially comply with SBA Loan Program Requirements;

(2) Previously participated in a material way with any past or present SBA Lender or Intermediary that failed to maintain satisfactory SBA performance;

(3) Previously defaulted on any Federal loan or Federally assisted financing that resulted in the Federal Government or any of its agencies or departments sustaining a loss in any of its programs; or

(4) Ever failed to pay when due any debt or obligation, including any amounts in dispute, to the Federal Government or guaranteed by the Federal Government (including but not limited to taxes or business or student loans).

■ 7. Add § 120.468 to read as follows:

§ 120.468 Change of ownership or control requirements for SBA Supervised Lenders.

(a) *SBA prior approval required.* Any change of ownership or control of an SBA Supervised Lender without SBA's prior written approval is prohibited. Prior to entering into any agreement, other than a non-binding letter of intent, for a change of ownership or control, SBA Supervised Lenders must receive SBA's prior written approval from the appropriate SBA official in accordance with the prevailing Delegations of Authority. An SBA Supervised Lender may not register proposed new owners on its books and records or permit them to participate in any manner in the conduct of the SBA Supervised Lender's affairs unless approved in writing by SBA. Any type of non-binding letter of intent regarding a prospective change of ownership or control must be reported to SBA within 30 calendar days. A change of ownership or control includes the following:

(1) Any transfer(s) (direct or indirect) of 10 percent or more of any class of the SBA Supervised Lender's stock or ownership interests (or series of transfers which, in the aggregate over an 18 month period, equals 10 percent or more), or any agreement providing for such transfer;

(2) Any transfer(s) (direct or indirect) that could result in the beneficial ownership by any person or group of persons acting in concert of 10 percent or more of any class of the SBA Supervised Lender's stock or ownership interests, or any agreement providing for such transfer(s);

(3) Any merger, consolidation, or reorganization;

(4) Any other transaction or agreement that transfers control of an SBA Supervised Lender; or

(5) Any other transaction or event that results in any change in the possession (direct or indirect) of the right to control, or the power to direct or cause the direction of, the management or policies of an SBA Supervised Lender, whether through the ownership of voting securities, by contract or otherwise.

(b) *Approval required by other regulatory authorities.* If a change of ownership or control of an SBA Supervised Lender is subject to the approval of any state or Federal chartering, licensing or other regulatory authority, copies of any documents filed with such authority must, at the same time, be transmitted to the appropriate SBA official in accordance with the prevailing Delegations of Authority. The approval of any state or Federal authority will be required in addition to SBA's prior written approval.

(c) *Application requirements for changes of ownership or control.* An applicant must submit a Lender Assessment Plan and a new application in accordance with § 120.466 for any change of ownership or control. If a proposed change of ownership is for less than 50 percent of the ownership interests in an SBA Supervised Lender, SBA may, in its sole discretion, limit the requirements of the Lender Assessment Plan or the complete application as set forth in official SBA policy and procedures.

(d) *Voluntary surrender of SBA lending authority.* An SBA Supervised Lender may voluntarily surrender its SBA lending authority (including its SBLC license or NFRL lending authority, as applicable) and withdraw as a participating Lender with SBA's prior written approval. The SBA Supervised Lender must agree to transfer its entire 7(a) loan portfolio to one or more Lenders acceptable to SBA in accordance with § 120.432(a), and enter into a withdrawal agreement to resolve any outstanding issues, including any outstanding monetary liabilities, to SBA's satisfaction. SBA may, in its sole discretion, take over the

servicing of an SBA Supervised Lender's 7(a) loan portfolio in accordance with § 120.535(d) upon the voluntary surrender of its SBA lending authority.

§ 120.470 [Amended]

■ 8. Amend § 120.470 by removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

■ 9. Amend § 120.471 by:

■ a. Revising paragraph (a);

■ b. Redesignating paragraphs (b)(3) through (5) as paragraphs (b)(4) through (6) respectively; and

■ c. Adding new paragraph (b)(3).

The revision and addition to read as follows:

§ 120.471 What are the minimum capital requirements for SBLCs?

(a) *Minimum capital requirements.* (1) Beginning on January 4, 2024, each SBLC that makes or acquires a 7(a) loan must maintain, at a minimum, unencumbered paid-in capital and paid-in surplus of at least $5,000,000, or 10 percent of the aggregate of its share of all outstanding loans, whichever is greater.

(2) Any SBLC approved on or after January 4, 2021, including in the event of a change of ownership or control, must maintain the minimum capital requirement set forth in paragraph (a)(1) of this section.

(3) Unless subject to paragraph (a)(1) or (2) of this section, an SBLC must comply with the minimum capital requirements that were in effect on January 3, 2021.

(b) * * *

(3) Unrestricted net assets (for non-profit corporations);

* * * * *

§ 120.475 [Removed and Reserved]

■ 10. Remove and reserve § 120.475.

Jovita Carranza,

Administrator.

[FR Doc. 2020–26307 Filed 12–3–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0425; Project Identifier 2016–NE–13–AD; Amendment 39–21346; AD 2020–25–04]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2016–24–08 for all Rolls-Royce Deutschland Ltd. & Co KG (RRD) RB211–Trent 875–17, RB211–Trent 877–17, RB211–Trent 884–17, RB211–Trent 884B–17, RB211–Trent 892–17, RB211–Trent 892B–17, and RB211–Trent 895–17 model turbofan engines. AD 2016–24–08 required repetitive inspections of the engine upper bifurcation nose fairing assembly and repair or replacement of any fairing assembly that fails inspection. This AD retains the requirements to perform repetitive inspections of the engine upper bifurcation nose fairing assembly and repair or replacement of any fairing assembly that fails inspection. As a terminating action to these inspections, this AD also requires the modification of the engine upper bifurcation nose fairing assembly. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 8, 2021.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 8, 2021.

ADDRESSES: For service information identified in this final rule, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE24 8BJ; phone: (+44) 1332 242424; fax: (+44) 1332 249936; email: *http://www.rolls-royce.com/contact/civil_team.jsp;* internet: *https://customers.rolls-royce.com/public/rollsroycecare.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0425.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0425; 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 AD, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7132; fax: (781) 238–7199; email: *Scott.M.Stevenson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2016–24–08, Amendment 39–18725 (81 FR 86567, December 1, 2016) (AD 2016–24–08). AD 2016–24–08 applied to all RR RB211–Trent 875–17, RB211–Trent 877–17, RB211–Trent 884–17, RB211–Trent 884B–17, RB211–Trent 892–17, RB211–Trent 892B–17, and RB211–Trent 895–17 model turbofan engines. The NPRM published in the **Federal Register** on June 24, 2019 (84 FR 29423). The NPRM was prompted by RRD developing a modification of the engine upper bifurcation nose fairing assembly that terminates the need for repetitive inspections of this part. In the NPRM, the FAA proposed to retain the requirements to perform repetitive inspections of the engine upper bifurcation nose fairing assembly and repair or replacement of any fairing assembly that fails inspection. As a terminating action, in the NPRM the FAA also proposed to require modification of the engine upper bifurcation nose fairing assembly. The FAA is issuing this AD to address the unsafe condition of these products.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2018–0088, dated April 18, 2018 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

Inspection of in-service Trent 800 engines identified cracking and/or material release from the upper bifurcation fairing, which mates to the aeroplane thrust reverser upper bifurcation forward fire seal. Both sets of hardware create the engine firewall to isolate the engine compartment fire zone, which is a firewall feature of the aeroplane type design. Damage (missing materials and holes/openings) to the upper bifurcation fairing creates a breach of the engine fire wall, which may decrease the effectiveness of the engine fire detection and suppression systems due to excess fan air entering the engine compartment fire zone. This could delay or prevent the fire detection and suppression system from functioning properly, and can result in an increased risk of prolonged burning, potentially allowing a fire to reach unprotected areas of the engine, strut and wing.

This condition, if not detected and corrected, could lead to an uncontrolled fire, possibly resulting in damage to, or loss of, the aeroplane.

To address this potential unsafe condition, RR published the NMSB to provide inspection instructions. Consequently, EASA issued AD 2016–0084 to require repetitive inspections of the upper bifurcation fairing and, depending on findings, accomplishment of applicable corrective action(s).

Since that [EASA] AD was issued, RR developed modification (mod) 72–J803, which introduces a revised upper bifurcation nose fairing assembly, featuring an additional support bracket assembly at the right hand seal land. RR also published the modification SB to provide instructions for in-service engines. This modification removes the need for repetitive inspections.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2016–0084, which is superseded, and requires a modification, which constitutes terminating action for the repetitive inspections required by this [EASA] AD.

You may obtain further information by examining the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0425.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from six commenters. The commenters were Rolls-Royce plc (RR); American Airlines (AAL); The Boeing Company (Boeing); Delta Air Lines, Inc. (DAL); and two individual commenters. Five commenters requested changes to this AD, which included adding or updating the unsafe condition, terminating action, installation prohibition, and credit for previous actions. One commenter requested clarification regarding on-wing rework. One commenter expressed support for the AD. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Remove Statement Indicating the Unsafe Condition Could Cause a Fire

Boeing requested that paragraph (e), Unsafe Condition, of this AD be revised to replace ''. . . could result in engine fire and damage to the airplane'' with ''. . . could result in reduced ability to detect and/or control an engine fire which could lead to damage to the airplane.'' Boeing reasoned that unsafe condition is not expected to cause an engine fire. Instead, when material is liberated from the engine upper bifurcation nose fairing assembly, the core zone fire detection and extinguishing may be less effective in the event of a fire. This is due to airflow that may be allowed to pass into the fire zone through an alternate path and at an unknown rate compared to the intended design.

The FAA partially agrees. The FAA agrees that a cracked engine upper bifurcation nose fairing assembly and material release would not lead to an engine fire. The unsafe condition of this AD, however, is not the cracking of the engine upper bifurcation nose fairing assembly and material release, but the resulting failure of the engine fire control system. Since the engine fire control system would be inadequate to detect and control an engine fire, regardless of cause, the resulting hazard is the engine fire and consequent damage to the airplane. The FAA did not change this AD.

Request To Clarify Engine Upper Bifurcation Nose Fairing Assembly With FRSJ739 Repair

DAL requested that Note 1 to paragraph (g)(3) of this AD be updated to clarify inspection if on-wing repair FRSJ739 was applied. DAL reasoned that RRD added a second sheet to Figure 1 when it published Revision 2 of RR Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AJ165, on August 21, 2018. This second sheet includes the entire length of the bracket in Zone A if on-wing repair FRSJ739 was applied. The proposed AD did not provide any distinctions for on-wing repair FRSJ739.

The FAA disagrees. As stated in Note 1 to paragraph (g)(3) of this AD, Figure 1 of RR Alert NMSB RB.211–72–AJ165, Revision 2, dated August 21, 2018, provides guidance on the engine upper bifurcation nose fairing assembly inspection locations. Operators are not required to use Figure 1 to comply with this AD. Therefore, this AD is not required to reference on-wing repair FRSJ739.

Request To Add Credit for Previous Actions Paragraph

DAL requested that the FAA add a Credit for Previous Actions paragraph to this AD for previous initial and repetitive inspections completed using RR Alert NMSB RB.211–72–AJ165, Initial Issue, dated March 31, 2016, required by AD 2016–24–08.

The FAA disagrees. AD 2016–24–08 and this AD do not require use of RR Alert NMSB RB.211–72–AJ165 to perform the initial and repetitive inspections. RR Alert NMSB RB.211–72–AJ165 is provided as guidance on engine upper bifurcation nose fairing assembly inspection locations. Therefore, this AD does not need to provide credit for inspections performed using RR Alert NMSB RB.211–72–AJ165. The FAA did not change this AD.

Request To Update Terminating Action With the Latest Service Information

AAL, Boeing, DAL, and an individual commenter requested that paragraph (h), Mandatory Terminating Action, of this AD be updated to include RR Service Bulletin (SB) RB.211–72–J803, Revision 2, dated April 1, 2019. The commenters reasoned that RR SB RB.211–72–J803, Revision 1, dated July 13, 2018, has been superseded by Revision 2, dated April 1, 2019. Boeing also suggested adding language that allows any later revisions of the service information to be equivalent action as RRD may publish further revisions.

The FAA agrees to revise the reference to RR SB RB.211–72–J803 in paragraph (h) of this AD from Revision 1, dated July 13, 2018, to Revision 2, dated April 1, 2019. The FAA disagrees with adding language that allows any later revisions of the service information. Since later revisions of the service information have not been published or reviewed by the agency, the FAA will not require their use.

With the update to RR SB RB.211–72–J803 in this AD from Revision 1, dated July 13, 2018, to Revision 2, dated April 1, 2019, the FAA determined the need to update the estimated costs to reflect the increase in labor hours from 2 work-hours to 8 work-hours for both on-wing and in-shop visits.

Request To Add On-Wing Mandatory Terminating Action

DAL requested that the on-wing rework instructions introduced in the Accomplishment Instructions, paragraph 3.D., of RR SB RB.211–72–J803, Revision 2, dated April 1, 2019, be included as an option for the mandatory terminating action to the AD. DAL

added that paragraph (i), Installation Prohibition, will ensure that de-modification of the engine upper bifurcation nose fairing assembly will not be possible once the reworked engine upper bifurcation nose fairing assembly is installed.

The FAA agrees that the on-wing rework instructions should be added as an option to the mandatory terminating action in addition to the in-shop rework procedure. RR SB RB.211–72–J803, Revision 2, dated April 1, 2019, provides an option to perform the on-wing rework instructions. As a result, operators can perform the rework in-shop or on-wing. The FAA added the on-wing rework instructions to the mandatory terminating action section of this AD.

The FAA also agrees that de-modification of the engine upper bifurcation nose fairing assembly will not be possible once the reworked engine upper bifurcation nose fairing assembly is installed. As noted in the following comment response, the FAA removed the installation prohibition proposed in the NPRM as the mandatory terminating actions requiring the modification of the engine upper bifurcation nose fairing assembly makes this installation prohibition unnecessary.

Request To Revise Installation Prohibition

RR and AAL requested that paragraph (i), Installation Prohibition, of the proposed AD be revised. Rolls-Royce was concerned if an upper bifurcation panel (upper bifurcation nose fairing assembly) is required to complete an on-wing repair, it will prevent the installation of the original panel without the part being modified to the later standard. AAL reasoned that a serviceable engine upper bifurcation nose fairing assembly that needs to be repaired or replaced per AD 2016–24–08, but has not been, may be removed during non-related maintenance. The FAA infers that RR's concern aligns with AAL reasoning that removal of a panel for on-wing activity, such as maintenance or repair unrelated to the rework, will make the part ineligible for installation. Therefore, AAL proposed that paragraph (i) of the proposed AD be revised to ''After the effective date of this AD, do not install an engine upper bifurcation nose fairing assembly, P/N FK25470, onto any engine that has or had an engine upper bifurcation nose fairing assembly, P/N KH75280, installed.''

The FAA agrees that the installation prohibition would prevent the installation of the engine upper bifurcation nose fairing assembly, P/N FK25470, onto any engine after the effective date of this AD, even for work unrelated to this AD. The mandatory terminating action requires the modification of engine upper bifurcation nose fairing assembly, P/N FK25470 and, as such, the installation prohibition is not necessary. The FAA removed the installation prohibition from this AD.

Support for the AD

An individual commenter expressed support for the AD as written.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed RR SB RB.211–72–J803, Revision 2, dated April 1, 2019; Revision 1, dated July 13, 2018; and Initial Issue, dated December 7, 2017. The service information describes procedures for modification of the engine upper bifurcation nose fairing assembly. 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 **ADDRESSES**.

Other Related Service Information

The FAA reviewed RR Alert NMSB RB.211–72–AJ165, Revision 2, dated August 21, 2018. The NMSB provides guidance on engine upper bifurcation nose fairing assembly inspection locations. The FAA also reviewed AMM TASK 70–20–02, Water Washable Fluorescent Penetrant Inspection (Maintenance Process 213), and OMat 632, high sensitivity fluorescent penetrant inspection. This service information provides guidance on performing a fluorescent penetrant inspection.

Costs of Compliance

The FAA estimates that this AD affects 70 engines installed on airplanes of U.S. registry. Based on updated information since publication of the NPRM, the FAA revised the estimated number of engines installed on airplanes of U.S. registry from 125 in the NPRM to 70 in this final rule.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect engine upper bifurcation nose fairing assembly.	3.25 work-hours × $85 per hour = $276.25 ...	$0	$276.25	$19,337.50
Modify engine upper bifurcation nose fairing assembly.	8 work-hours × $85 per hour = $680	50	730	51,100

The FAA estimates the following costs to do any necessary repairs or replacements that would be required based on the results of the mandated inspections. The agency has no way of determining the number of engines that might need these repairs or replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair engine upper bifurcation nose fairing assembly	8 work-hours × $85 per hour = $680	$500	$1,180

ON-CONDITION COSTS—Continued

Action	Labor cost	Parts cost	Cost per product
Replace engine upper bifurcation nose fairing assembly.	30 work hours × $85 per hour = $2,550	500	3,050

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing airworthiness directive AD 2016–24–08, Amendment 39–18725 (81 FR 86567, December 1, 2016); and

■ b. Adding the following new airworthiness directive:

2020–25–04 Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce plc): Amendment 39–21346; Docket No. FAA–2019–0425; Project Identifier 2016–NE–13–AD.

(a) Effective Date

This airworthiness directive (AD) is effective January 8, 2021.

(b) Affected ADs

This AD replaces AD 2016–24–08, Amendment 39–18725 (81 FR 86567, December 1, 2016).

(c) Applicability

This AD applies to all Rolls-Royce Deutschland Ltd. & Co KG (RRD) (Type Certificate previously held by Rolls-Royce plc) RB211–Trent 875–17, RB211–Trent 877–17, RB211–Trent 884–17, RB211–Trent 884B–17, RB211–Trent 892–17, RB211–Trent 892B–17, and RB211–Trent 895–17 model turbofan engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7130, Engine Fireseals.

(e) Unsafe Condition

This AD was prompted by RRD developing a modification of the engine upper bifurcation nose fairing assembly as a result of reports of cracking and material release from an engine upper bifurcation fairing. The FAA is issuing this AD to prevent failure of the engine fire control system. The unsafe condition, if not addressed could result in engine fire and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) Within 7,500 engine flight hours (FHs) since new or since the last inspection or within 150 flight cycles (FCs) after January 5, 2017 (the effective date of AD 2016–24–08), whichever occurs later, inspect the engine upper bifurcation nose fairing assembly for cracks or missing material. Use paragraph (g)(3) of this AD to perform the inspection.

(2) Repeat the inspection required by paragraph (g)(1) of this AD within every 7,500 engine FHs since the last inspection.

(3) Inspect the engine upper bifurcation nose fairing assembly as follows.

Note 1 to Paragraph (g)(3): Figure 1 of Rolls-Royce plc (RR) Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AJ165, Revision 2, dated August 21, 2018, provides guidance on the engine upper bifurcation nose fairing assembly inspection locations.

(i) Visually inspect upper bifurcation fairing seal face 22, seal support 23, and Zone A for any cracks or material loss on the right side.

(A) If fairing seal face 22 is found to have released material, repair or replace the fairing before further flight.

(B) If there is a single crack found on fairing seal face 22, shorter than 6 mm, repair or replace the fairing within 100 engine FCs, or at the next engine shop visit, whichever occurs first.

(C) If there is a single crack, longer than 6 mm, found on fairing seal face 22, repair or replace the fairing within 15 engine FCs or at the next engine shop visit, whichever occurs first.

(D) If there are two or more cracks found on fairing seal face 22, replace the fairing within 15 engine FCs or at the next engine shop visit, whichever occurs first.

(E) If there is any cracking or material loss found on seal support 23, replace the fairing within 15 engine FCs or at the next engine shop visit, whichever occurs first.

(ii) If the visual inspection required by paragraph (g)(3)(i) of this AD does not detect any cracks, fluorescent penetrant inspect Zone A.

(A) If a crack shorter than 6 mm is detected, repair or replace the fairing within 100 engine FCs, or at the next engine shop visit, whichever occurs first.

(B) If a crack longer than 6 mm is detected, repair or replace the fairing within 15 engine FCs or at the next engine shop visit, whichever occurs first.

Note 2 to Paragraph (g)(3)(ii): AMM TASK 70–20–02, Water Washable Fluorescent Penetrant Inspection (Maintenance Process 213), and OMat 632, high sensitivity fluorescent penetrant inspection, provides guidance on performing a fluorescent penetrant inspection.

(h) Mandatory Terminating Action

As a mandatory terminating action to the inspections of the engine upper bifurcation nose fairing assembly required by paragraph (g) of this AD, perform one of the following:

(1) At the next engine shop visit after the effective date of this AD, modify the engine upper bifurcation nose fairing assembly in

accordance with the Accomplishment Instructions, paragraph 3.C., of RR Service Bulletin (SB) RB.211–72–J803, Revision 2, dated April 1, 2019; paragraph 3.B., Revision 1, dated July 13, 2018; or paragraph 3.B., Original Issue, dated December 7, 2017; or

(2) Before the next engine shop visit after the effective date of this AD, modify the engine upper bifurcation nose fairing assembly in accordance with the Accomplishment Instructions, paragraph 3.D., of RR SB RB.211–72–J803, Revision 2, dated April 1, 2019.

(i) Definition

For the purpose of this AD, an ''engine shop visit'' is defined as the induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine flanges, except that the separation of engine flanges solely for the purposes of transportation without subsequent engine maintenance does not constitute an engine shop visit.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in Related Information. 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.

(k) Related Information

(1) For more information about this AD, contact Scott Stevenson, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7132; fax: (781) 238–7199; email: *Scott.M.Stevenson@faa.gov.*

(2) Refer to European Aviation Safety Agency (EASA) AD 2018–0088, dated April 18, 2018, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0425.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Rolls-Royce plc (RR) Service Bulletin (SB) RB.211–72–J803, Revision 2, dated April 1, 2019.

(ii) RR SB RB.211–72–J803, Revision 1, dated July 13, 2018.

(iii) RR SB RB.211–72–J803, Initial Issue, dated December 7, 2017.

(3) For RR service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE24 8BJ; phone: (+44) 1332 242424; fax: (+44) 1332 249936; email: *http://www.rolls-royce.com/contact/civil_team.jsp;* internet: *https://customers.rolls-royce.com/public/rollsroycecare.*

(4) You may view this service information at 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.

(5) You may view this service information that is incorporated by reference 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: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 30, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–26730 Filed 12–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31343 Amdt. No. 3933]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or removes Standard Instrument Approach Procedures (SIAPS) and associated Takeoff Minimums and Obstacle Departure procedures (ODPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 4, 2020. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 4, 2020.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops–M30. 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, 8260–15B, when required by an entry on 8260–15A, and 8260–15C.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the **Federal**

Register expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their graphic depiction on charts printed by publishers or aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the typed of SIAPS, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

The circumstances that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

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 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. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Lists of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC on November 27, 2020.

Wade Terrell,

Aviation Safety Manager, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CRF part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure Procedures effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

Effective 31 December 2020

Kiana, AK, Bob Baker Memorial, RNAV (GPS) RWY 6, Orig-D, CANCELLED
Kiana, AK, PAIK, RNAV (GPS) RWY 25, Amdt 1
Kiana, AK, Bob Baker Memorial, RNAV (GPS)-A, Orig
Le Mars, IA, KLRJ, RNAV (GPS) RWY 18, Amdt 2
Le Mars, IA, KLRJ, RNAV (GPS) RWY 36, Amdt 1C
Le Mars, IA, Le Mars Muni, Takeoff Minimums and Obstacle DP, Amdt 3
Waverly, IA, C25, RNAV (GPS) RWY 11, Orig
Waverly, IA, C25, RNAV (GPS) RWY 29, Orig
Waverly, IA, Waverly Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Waverly, IA, Waverly Muni, VOR–A, Amdt 4, CANCELLED
Churchville, MD, 0W3, RNAV (GPS)-B, Orig-B
Laconia, NH, KLCI, ILS OR LOC RWY 8, Amdt 2
New York, NY, KJFK, ILS OR LOC RWY 22L, ILS RWY 22L (CAT II), ILS RWY 22L (CAT III), Amdt 26
New York, NY, KJFK, ILS OR LOC RWY 22R, Amdt 4
Clarion, PA, KAXQ, RNAV (GPS) RWY 6, Amdt 1B
Clarion, PA, KAXQ, RNAV (GPS) RWY 24, Amdt 1C
Amarillo, TX, Rick Husband Amarillo Intl, RADAR–1, Amdt 16A
Midland, TX, Midland Intl Air and Space Port, RADAR–1, Amdt 7A
Sinton, TX, T69, RNAV (GPS) RWY 14, Orig-B
Sinton, TX, T69, RNAV (GPS) RWY 32, Orig-B
Sinton, TX, T69, VOR RWY 14, Amdt 1C
Kenosha, WI, KENW, RNAV (GPS) RWY 7L, Amdt 1
Kenosha, WI, KENW, RNAV (GPS) RWY 25R, Amdt 1
Kenosha, WI, Kenosha Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1
Cody, WY, KCOD, RNAV (GPS) RWY 4, Amdt 1
Cody, WY, KCOD, RNAV (GPS) RWY 22, Amdt 3

Rescinded: On November 02, 2020 (85 FR 69149), the FAA published an Amendment in Docket No. 31337 Amdt No. 3927, to Part 97 of the Federal Aviation Regulations under section 97.23, and 97.37. The following entries for King Salmon, AK, Bardstown, KY, and Campbellsville, KY, effective December 31, 2020, are hereby rescinded in their entirety:

King Salmon, AK, King Salmon, Takeoff Minimums and Obstacle DP, Amdt 2
Bardstown, KY, Samuels Field, VOR RWY 3, Amdt 1, CANCELLED
Campbellsville, KY, Taylor County, VOR/DME–A, Amdt 7, CANCELLED

Rescinded: On November 13, 2020 (85 FR 72560), the FAA published an Amendment in Docket No. 31339 Amdt No. 3929, to Part 97 of the Federal Aviation Regulations under section 97.25, 97.23, and 97.33. The following entries for, Elizabethtown, KY, Louisville, KY, and Petersburg, WV, effective December 31, 2020, are hereby rescinded in their entirety:

Elizabethtown, KY, KEKX, RNAV (GPS) RWY 5, Amdt 1
Elizabethtown, KY, KEKX, RNAV (GPS) RWY 23, Orig-B
Elizabethtown, KY, Addington Field, VOR–A, Amdt 3A, CANCELLED
Louisville, KY, KSDF, LOC RWY 29, Amdt 1A
Petersburg, WV, W99, RNAV (GPS) Y RWY 31, Orig-B
Petersburg, WV, W99, RNAV (GPS) Z RWY 31, Orig-B

Rescinded: On November 24, 2020 (85 FR 74860), the FAA published an Amendment in Docket No. 31341 Amdt No. 3931, to Part

97 of the Federal Aviation Regulations under section 97.23, 97.27, and 97.33. The following entries for Courtland, AL, Bentonville, AR, Orlando, FL, Mc Rae, GA, Marion, IL, Memphis, TN, and Millington, TN, effective December 31, 2020, are hereby rescinded in their entirety:

Courtland, AL, Courtland, VOR RWY 13, Amdt 1B, CANCELLED

Bentonville, AR, Bentonville Muni/Louise M Thaden Field, VOR–A, Amdt 14, CANCELLED

Orlando, FL, Kissimmee Gateway, VOR/DME–A, Amdt 1, CANCELLED

Mc Rae, GA, Telfair-Wheeler, NDB RWY 21, Amdt 10A, CANCELLED

Marion, IL, KMWA, RNAV (GPS) RWY 2, Amdt 1D

Marion, IL, KMWA, RNAV (GPS) RWY 20, Amdt 1D

Memphis, TN, General Dewitt Spain, VOR RWY 17, Orig-B, CANCELLED

Millington, TN, Charles W Baker, VOR RWY 18, Amdt 2A, CANCELLED

[FR Doc. 2020–26689 Filed 12–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31344; Amdt. No. 3934]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective December 4, 2020. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 4, 2020.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC, 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Navigation Products, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. 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: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg 29 Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section. The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

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 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. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC on November 27, 2020.

Wade Terrell,

Aviation Safety, Manager, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, CFR part 97, (is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

Effective Upon Publication

AIRAC Date	State	City	Airport	FDC No.	FDC Date	Subject
31-Dec-20	VA	Norfolk	Hampton Roads Executive	0/0181	11/16/20	ILS OR LOC RWY 10, Orig-A.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2524	11/18/20	RNAV (RNP) Z RWY 29, Orig-F.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2525	11/18/20	RNAV (RNP) Y RWY 29, Amdt 1D.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2576	11/18/20	RNAV (GPS) Z RWY 22L, Amdt 2C.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2581	11/18/20	RNAV (GPS) Y RWY 4R, Amdt 1F.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2582	11/18/20	RNAV (GPS) RWY 22R, Amdt 1E.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2583	11/18/20	RNAV (GPS) RWY 11, Orig-F.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2584	11/18/20	RNAV (GPS) RWY 4L, Amdt 2E.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2585	11/18/20	ILS OR LOC RWY 22R, Amdt 6B.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2587	11/18/20	ILS OR LOC RWY 22L, Amdt 13C.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2601	11/18/20	ILS OR LOC RWY 11, Amdt 2E.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2602	11/18/20	ILS OR LOC RWY 4R, Amdt 13A.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2604	11/18/20	ILS OR LOC RWY 4L, Amdt 15A.
31-Dec-20	NJ	Newark	Newark Liberty Intl	0/2605	11/18/20	RNAV (GPS) X RWY 29, Orig-A.
31-Dec-20	MN	Tracy	Tracy Muni	0/3203	11/19/20	Takeoff Minimums and Obstacle DP, Orig.
31-Dec-20	MI	Grand Rapids	Gerald R Ford Intl	0/5806	11/19/20	RNAV (GPS) RWY 17, Amdt 1B.
31-Dec-20	OK	Ardmore	Ardmore Muni	0/6707	11/10/20	RNAV (GPS) RWY 31, Amdt 1C.
31-Dec-20	CA	Madera	Madera Muni	0/8852	11/19/20	Takeoff Minimums and Obstacle DP, Amdt 5.

[FR Doc. 2020–26690 Filed 12–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 187

[Docket No.: FAA–2020–1002]

Policy Clarifying Collection and Enforcement of Overflight Fees

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Statement of enforcement policy.

SUMMARY: This document announces that the FAA will pursue all delinquent balances for overflight fees including the collection of interest, penalties, and administrative charges as authorized by law.

DATES: This policy is effective January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Michelle Leissner, Financial Service Division, Office of General Accounting, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 S MacArthur Blvd., Oklahoma City, OK 73169; telephone: (405) 954–9984; email: *michelle.leissner@faa.gov.*

SUPPLEMENTARY INFORMATION:

Availability of This Policy

You can obtain an electronic copy using the internet by—

(1) Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);

(2) Visiting the FAA's Regulations and Policies web page at *http://www.faa.gov/regulations_policies/;* or

(3) Accessing the **Federal Register**'s website at *https://www.federalregister.gov/.*

You can also obtain a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Make sure to identify the docket number of this policy.

Background

The FAA must collect fees for air traffic control and related services it provides to aircraft other than military and civilian aircraft of the United States Government or of a foreign government that neither take off from, nor land in, the United States. 49 U.S.C. 45301(a). Title 14 CFR part 187 implements the requirement by prescribing the collection of the fees for such flights that transit United States-controlled airspace (commonly known as ''overflights''). 14 CFR 187.51. The FAA implemented overflight fees in their current form in 2001. *Fees for FAA Services for Certain Flights* final rule, 66 FR 43680 (Aug. 20, 2001). The FAA last updated part 187 in 2016. *Update of Overflight Fee Rates* final rule, 81 FR 85843 (Nov. 29, 2016).

In its 2001 final rule, the FAA stated it would assess administrative charges and interest for delinquent invoices in accordance with 49 CFR part 89. See 66 FR at 43716. The FAA also stated it would pursue all delinquent balances to the extent provided by law. *Id.* Part 89, which contains Department of Transportation (DOT) provisions implementing the Federal Claims Collection Act (31 U.S.C. 3701–3720), sets forth the procedures by which the DOT collects certain claims owed to the United States, and determines and collects interest and other charges on those claims. Section 89.23 requires the FAA, by DOT delegation in § 89.5(c), to charge interest at the Treasury Current Value of Funds Rate (or higher) from the due date, to waive interest charges on debts paid within 30 calendar days of the due date, to charge a late payment penalty of six percent on any portion of the debt that is more than 90 days past due, and to assess administrative charges to cover additional costs incurred in processing and handling the debt beyond the payment due date. While the FAA has collected costs aggressively on the delinquent debts associated with overflight fees, the FAA has not pursued charging interest, late payment penalties, or administrative costs on delinquent debts.

Discussion of the Notification of Enforcement Policy

In accordance with 49 CFR 89.23, the FAA will enforce its rules regarding the collection of interest, administrative charges, and late payment penalties on delinquent overflight fee invoices. The agency will update invoices, consistent with 49 CFR 89.21, to include the interest, penalties, and administrative charges applicable to the billed amount and the date on which these charges begin to accrue. Charging interest, administrative charges, and penalties will compensate the Government for the loss of use of funds when a debt is not paid timely, discourage delinquencies, encourage early payment of the delinquent debt in full, and cover the expenses associated with collecting a debt.

In accordance with 49 CFR 89.23, interest on debt will begin to accrue on an outstanding debt at the Treasury Current Value of Funds Rate on the calendar date following the specified due date of the debt. Interest on debt will accrue only on the principal of the debt (simple interest) at a fixed rate and will accrue until payment is received. The FAA will waive interest on debt that is paid within 30 calendar days from the due date. 49 CFR 89.23(c).

Administrative charges will consist of a fixed fee of $16. The FAA will compute these charges to cover the cost of processing and handling delinquent debt. The FAA sends to debtors a total of three progressively-stronger written demand letters consistent with 49 CFR 89.21: An invoice, a delinquency notice, and a Treasury referral notification letter. The invoice includes the due date and debt amount. The FAA sends a delinquency notice to a debtor if the debt remains unpaid by the due date. If the debt remains unpaid 30 days past due date, the FAA sends the debtor a Treasury referral notification letter stating that any portion of the debt that is not paid within another 15 days (45 days from the due date) will be referred to the Treasury for collection. The FAA will refer the debt to Treasury when the debt remains unpaid for 45 days after the due date. The fixed $16 charge represents the average cost to the FAA to process and handle delinquency notices, Treasury referral notification letters, or Treasury referrals, including labor, mailing, and overhead costs. The FAA will assess the $16 charge each time the FAA sends delinquency notices, sends Treasury referral notification letters, or refers the debt to the Treasury for collection. The FAA prepared a *White Paper on Administrative Charges Applied to Delinquent Overflight Fee Invoices* that explains the $16 amount. The paper is available in the public docket that contains this Notification.

The FAA is authorized to charge a penalty on any portion of delinquent debt that is more than 90 days past due. 49 CFR 89.23(a). The FAA sends any delinquent debt to the Treasury for collection before the debt becomes more than 90 days past due. For bills that remain unpaid more than 90 days past due, the FAA applies—and the Treasury Department implements—the six percent penalty. In all cases of referred debt, Treasury applies its own collection charges, which are separate from FAA's penalty charges.

Issued in Washington, DC, on November 23rd, 2020.

Nathan Tash,

Acting Assistant Administrator for Finance and Management.

[FR Doc. 2020–26251 Filed 12–2–20; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230, 232, 240, 249, and 270

[Release Nos. 33–10889; 34–90441; 39–2534; IC–34096]

Electronic Signatures in Regulation S–T Rule 302

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: We are adopting amendments to Regulation S–T and the Electronic Data Gathering, Analysis, and Retrieval system (''EDGAR'') Filer Manual (''EDGAR Filer Manual'' or ''Filer Manual'') to permit the use of electronic signatures in signature authentication documents required under Regulation S–T in connection with electronic filings on EDGAR that are required to be signed. We are also adopting corresponding revisions to several rules and forms under the Securities Act of 1933 (''Securities Act''), Securities Exchange Act of 1934 (''Exchange Act''), and Investment Company Act of 1940 (''Investment Company Act'') to permit the use of electronic signatures in signature authentication documents in connection with certain other filings.

DATES: Effective December 4, 2020. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Charles Kwon, Office of Rulemaking, at (202) 551–3430, Division of Corporation Finance; Terri Jordan, Office of Rulemaking, at (202) 551–6792, Division of Investment Management; or Devin Ryan, Office of Chief Counsel, at (202) 551–5550, Division of Trading and Markets; U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: We are adopting amendments to the following rules and forms to permit the use of electronic signatures in signature authentication documents in connection with certain specified filings, including electronic filings on EDGAR:

Commission reference	CFR citation (17 CFR)
Securities Act [1]:	
Securities Act Rule 402	§ 230.402.
Securities Act Rule 471	§ 230.471.
Regulation S–T	§§ 232.10 through 232.903.
Rule 301	§ 232.301.
Rule 302	§ 232.302.
Exchange Act [2]:	
Exchange Act Rule 12b–11.	§ 240.12b–11.
Exchange Act Rule 14d–1.	§ 240.14d–1.
Exchange Act Rule 15Fb1–1.	§ 240.15Fb1–1.
Exchange Act Rule 16a–3.	§ 240.16a–3.
Form CB	§ 249.480.
Investment Company Act:	
Investment Company Act Rule 8b–11.	§ 270.8b–11.

We are also adopting an updated EDGAR Filer Manual, Volume II: ''EDGAR Filing'' (Version 55) (November 2020) that sets forth certain requirements that the electronic signing process must meet when electronic signatures are used. The updated Filer Manual is incorporated by reference into the Code of Federal Regulations.[3]

I. Discussion

Regulation S–T, in conjunction with the EDGAR Filer Manual and other applicable rules, regulations, and forms, governs the electronic submission of documents filed with or otherwise submitted to the Securities and Exchange Commission (the ''Commission'') through EDGAR.[4] Title 17, section 232.302(b) (Rule 302(b)) currently requires that each signatory to an electronic filing manually sign a signature page or other document (''authentication document'') before or at the time of the electronic filing to authenticate, acknowledge, or otherwise adopt the signature that appears in typed form within the electronic filing.[5] An electronic filer must retain the authentication document with respect to each signatory to the electronic filing for a period of five years and must furnish a copy of it to the Commission or its staff upon request.[6]

The Commission has stated that the authentication document requirement in Rule 302(b) ''was established to provide a satisfactory means by which signatories could authenticate and adopt their typed signatures appearing on filed documents for evidentiary purposes.'' [7] In March 2020, the Commission staff provided its views on, among other things, complying with this requirement when considering the public health and safety concerns related to COVID–19.[8] In April 2020, the Commission received a rulemaking petition requesting that we permit the use of electronic signatures when executing authentication documents under Rule 302(b).[9] The rulemaking petition states, among other things, that ''the current COVID–19 situation has . . . significantly increased the difficulties associated with obtaining manual 'wet' signatures'' and that ''[i]mprovements in electronic signature software technology make it possible to confirm (with at least equal confidence to the collection of manual signatures) who has signed a document and when it was signed.'' In June 2020, nearly 100 public companies jointly

[1] 15 U.S.C. 77a *et seq.*

[2] 15 U.S.C. 78a *et seq.*

[3] 17 CFR 232.301.

[4] Rule 10(a) of Regulation S–T [17 CFR 232.10a]. The EDGAR Filer Manual contains the technical specifications needed for filers to make submissions through the EDGAR system. The Commission originally adopted the EDGAR Filer Manual on April 1, 1993, with an effective date of April 26, 1993. *Adoption of EDGAR Filer Manual,* Release No. 33–6986 (Apr. 1, 1993) [58 FR 18638 (Apr. 9, 1993)]. The amendments adopted in this rulemaking do not apply to the notarized signature requests for EDGAR access pursuant to the requirements of Rule 10(b) of Regulation S–T. Moreover, the authentication document discussed herein is distinct from the authentication document referenced in Volume I of the Filer Manual in connection with Rule 10(b) notarized authentication documents.

[5] Pursuant to Rule 302(a) of Regulation S–T, signatures required in any electronic submission must be in typed form.

[6] *See* Rule 302(b) of Regulation S–T. As discussed below, certain rules and forms under the Securities Act and the Exchange Act also require authentication documents in connection with certain filings when these filings contain typed, rather than manual, signatures. References to ''authentication documents'' in this release refers to such documents as required by Rule 302(b) or these other rules and forms, as the context requires.

[7] *Application of the Electronic Signatures in Global and National Commerce Act to Record Retention Requirements Pertaining to Issuers under the Securities Act of 1933, Securities Exchange Act of 1934 and Regulation S–T,* Release No. 33–7985 (June 14, 2001) [66 FR 33175 (June 21, 2001)] (citing *Rulemaking for EDGAR System,* Release No. 33–6977, Section III.F.2 (Feb. 23, 1993) [58 FR 14628 (Mar. 18, 1993)]). In the 2001 release, the Commission issued guidance stating that the requirements to retain authentication documents are not subject to the Electronic Signatures in Global and National Commerce Act (''E–SIGN Act''), because ''authentication documents are records generated principally for governmental purposes rather than in connection with a business, consumer or commercial transaction.''

[8] *See* Staff Statement Regarding Rule 302(b) of Regulation S–T in Light of COVID–19 Concerns (Mar. 24, 2020), *available at https://www.sec.gov/corpfin/announcement/rule-302b-regulation-s-t-covid-19-update.*

[9] Specifically, the rulemaking petition requested that the Commission amend Rule 11 and Rule 302 of Regulation S–T, as well as any other necessary rules and forms, to permit the use of electronic signatures in addition to manual signatures when executing authentication documents under Rule 302 and to provide that authentication documents may be retained physically or electronically for the requisite five-year period. *See* letter from Wilson Sonsini Goodrich & Rosati, Fenwick & West LLP, and Cooley LLP, *available at https://www.sec.gov/rules/petitions/2020/petn4-760.pdf.*

submitted a letter in support of the rulemaking petition.[10]

After considering the widespread use of electronic signatures and technological developments in the authentication and security of electronic signatures,[11] and the issues raised in the rulemaking petition, we have reevaluated the requirement that signatories may only manually sign authentication documents under Rule 302(b). As a result, we are amending Rule 302(b) to permit a signatory to an electronic filing who follows certain procedures discussed herein to sign an authentication document through an electronic signature that meets certain requirements specified in the EDGAR Filer Manual.[12] This amendment will provide additional flexibility in complying with the authentication document requirement by providing signatories with the option of signing an authentication document either manually or electronically, while requiring the signing process for an electronic signature to meet certain conditions that are consistent with the evidentiary purposes of the authentication document. The existing requirements of Rule 302(b) will be otherwise unchanged, including the requirements that an electronic filer retain the authentication document for a period of five years and furnish a copy of it upon request to the Commission or its staff.[13]

We are setting forth the requirements for the electronic signature signing process in the EDGAR Filer Manual, which will specify that, when a signatory signs an authentication document using an electronic signature, the signing process for the electronic signature must, at a minimum:

- Require the signatory to present a physical, logical, or digital credential that authenticates the signatory's individual identity;
- Reasonably provide for non-repudiation of the signature;
- Provide that the signature be attached, affixed, or otherwise logically associated with the signature page or document being signed; and
- Include a timestamp to record the date and time of the signature.[14]

These requirements are intended to be technologically neutral and allow for different types and forms of electronic signatures, provided that the signing process satisfies a number of conditions that relate to the validity and enforceability of an electronic signature. The signing process must incorporate a security procedure that requires the authentication of a signatory's individual identity through a physical, logical, or digital credential, and the signing process must reasonably provide for the non-repudiation of the electronic signature. The signing process requirements also provide that the signature be logically associated with the signature page or document being signed, thereby providing the signatory with notice of the nature and substance of the document and an opportunity to review it before signing, and that the electronic signature be linked to the signature page or document in a manner that allows for later confirmation that the signatory signed the signature page or document. Finally, given that a signatory must execute an authentication document pursuant to Rule 302(b) before or at the time an electronic filing is made, the signing process must include a timestamp that records the date and time of the electronic signature.

We have included a requirement in new Rule 302(b)(2) that, before a signatory initially uses an electronic signature to sign an authentication document, the signatory must manually sign a document attesting that the signatory agrees that the use of an electronic signature in any authentication document constitutes the legal equivalent of such individual's manual signature for purposes of authenticating the signature to any filing for which it is provided (''initial electronic signature authentication document'').[15] An electronic filer must retain this manually signed document for as long as the signatory may use an electronic signature to sign an authentication document and for a minimum period of seven years after the date of the most recent electronically signed authentication document. Pursuant to Rule 302(b)(3), the electronic filer shall furnish a copy of it upon request to the Commission or its staff.[16]

In addition, we are amending certain rules and forms under the Securities Act, Exchange Act, and Investment Company Act to allow the use of electronic signatures in authentication documents in connection with certain other filings when these filings contain typed, rather than manual, signatures.[17] These amendments extend comparable treatment to these filers in allowing electronically signed authentication documents under generally the same conditions applicable to electronic filers under Rule 302(b).[18]

Along with the adoption of an updated EDGAR Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of the current revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The updated EDGAR Filer Manual is available at *https://www.sec.gov/info/edgar/edmanuals.htm.* The EDGAR Filer Manual also is available for website viewing and printing in the

[10] *See* comment letter from Richard Blake, *et al., available at https://www.sec.gov/comments/4-760/4760-7278993-217809.pdf.* We have not received any letters that oppose the rulemaking petition.

[11] *See* discussion in Section IV. Economic Analysis *infra.*

[12] We are also adopting amendments to Rule 302(a) of Regulation S–T to update the definition of ''signature,'' by revising ''electronic entry'' to ''computer representation,'' ''letters'' to ''symbols,'' and by removing references to obsolete terminology (''magnetic impulse''). This amendment does not change the substance or intended meaning of the definition.

[13] *See* new Rules 302(b)(1) and (b)(3).

[14] For purposes of the process requirements underlying the electronic signature of authentication documents, we are defining the terms ''electronic signature,'' ''credential,'' and ''non-repudiation'' in the EDGAR Filer Manual. The term ''electronic signature'' is defined as an electronic sound, symbol, or process, attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. While this definition is consistent with the widely used definition of the term ''electronic signature'' in the E–SIGN Act, 15 U.S.C. 7006, we continue to believe that the E–SIGN Act does not apply to the Commission's requirements related to authentication documents. *See supra* note 7. The term ''credential'' is defined as an object or data structure exclusively possessed and controlled by an individual to assert identity and provide for authentication. The term ''non-repudiation'' is defined as assurance that an individual cannot falsely deny having performed a particular action.

[15] *See* new Rule 302(b)(2). Additionally, Section 6(a) of the Securities Act provides that signatures to any Securities Act registration statement shall be presumed to have been written by authority of the person(s) who signed it, and the burden of proof, in the event such authority shall be denied, shall be upon the denying party. *See* 15 U.S.C. 77f(a).

[16] A manually signed document under Rule 302(b), including an initial electronic signature authentication document or a manually signed authentication document, may be stored via electronic means. *See* new Rule 302(b)(3).

[17] Securities Act Rules 402(e) and 471(b); Exchange Act Rules 12b–11(d), 14d–1(h), 16a–3(i) and, 15Fb1–1; Form CB; and Investment Company Act Rule 8b–11. Rules 402(e), 471(b), 12b–11(d), 14d–1(h); 16a–3(i); and 8b–11 allow manual, typed, duplicated, or faxed signatures on paper filings, with a manual signature retention requirement for typed, duplicated, or faxed signatures. *See Phase One Recommendation of Task Force on Disclosure Simplification,* Release No. 33–7300 (May 31, 1996) [61 FR 30397 (June 14, 1996)] at 30400 (stating that the Commission was adopting these requirements ''to provid[e] comparable treatment to both paper and electronic filers'' with respect to the signature and authentication requirements). The signature requirements in Rules 12b–11(d) and 14d–1(h) apply solely with respect to the scope of regulation defined in Rules 12b–11 and 14d–1(a), respectively.

[18] The amendments to these rules include a cross reference to the requirements set forth in Rule 302(b) of Regulation S–T.

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.

II. Procedural and Other Matters

The Administrative Procedure Act (''APA'') generally requires an agency to publish notice of a rulemaking in the **Federal Register** and provide an opportunity for public comment.[19] This requirement does not apply, however, to rules of agency organization, procedure, or practice,[20] or if the agency ''for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' [21] We find that these amendments relate to agency procedures or practice and do not substantially alter the rights and obligations of non-agency parties. We also find that notice and comment are unnecessary because the amendments merely provide an optional alternative method for signatories to sign authentication documents pursuant to Rule 302(b) and corresponding provisions in our rules and forms. It follows that the amendments do not require analysis under the Regulatory Flexibility Act or a report to Congress under the Small Business Regulatory Fairness Act.[22]

The APA generally requires that an agency publish an adopted rule in the **Federal Register** at least 30 days before it becomes effective.[23] This requirement, however, does not apply if the agency finds good cause for making the rule effective sooner.[24] For the same reasons we are forgoing notice and comment, the Commission finds good cause to make these amendments effective upon publication in the **Federal Register**. We further believe signatories and electronic filers should have the option of using electronic signatures in authentication documents as soon as practicable and find there is good cause for these amendments to take effect upon publication in the **Federal Register**. We also believe the amendments relieve a restriction in that execution of authentication documents no longer will be limited to manual or ''wet'' signatures.[25]

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.

III. Paperwork Reduction Act

Certain provisions of our rules and forms contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[26] The hours and costs associated with preparing and filing forms and retaining records—including those associated with signature authentication requirements—constitute reporting and cost burdens imposed by the collection of information requirements. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information requirement unless it displays a currently valid Office of Management and Budget control number. Compliance with the information collections is mandatory. The paperwork burden associated with the Commission's signature authentication requirements is imposed through the forms that are subject to those requirements and is reflected in the analysis of those forms. Responses to these information collections are not kept confidential and there is no mandatory retention period for the information disclosed, although filers are required to retain an authentication document for a period of five years.

As noted above, the amendments do not substantively alter the authentication document requirements, but rather provide an optional alternative method for signatories to sign authentication documents electronically. Although the requirements underlying the use of an electronic signature differ somewhat from those for use of a manual signature in connection with an authentication document (*e.g.,* an initial electronic signature authentication document will be required to be retained for seven years), on balance, we expect the amendments to incrementally ease the burden associated with executing such a document. It is difficult to predict how many filers will take advantage of the alternative signing method; however, we expect a filer would utilize this optional method only if it determines that the burdens of this alternative method are less than existing methods. Given the incremental nature of the amendments and in order to avoid overestimating any potential reduction in paperwork burdens, we are not revising any burden and cost estimates in connection with these amendments.

IV. Economic Analysis

The final amendments provide signatories with additional flexibility in connection with documents filed with the Commission, including electronic filings made on EDGAR, by permitting the use of electronic signatures in authentication documents. Due to technological advances that have enabled electronic signatures to become as credible as their manual, ''wet'' counterparts and the potential for efficiency gains, we believe providing such flexibility is justified. Below, we consider the benefits and costs, as well as the effects on efficiency, competition, and capital formation that we anticipate will result from the final amendments.[27] We evaluate the economic effects of the amendments relative to a baseline which includes the current regulatory requirements applicable to filers and signatories, as discussed in Section I above, as well as current practices. These requirements apply to both electronic and paper filers. The vast majority of Commission filings must be made electronically.[28] Based on information from 2019, the Commission received approximately 644,000 electronic filings from approximately 131,000 filers. By contrast staff analysis of filings in EDGAR identified 4,881 scanned paper filings from 2,603 filers in 2019.

Developments in cryptography and computing have enabled the development of digital signatures that are at least as credible as manual signatures. Digital signatures available today can: (i) Assure users that signed documents have not been altered; (ii) identify the signatory; and (iii) make it

[19] *See* 5 U.S.C. 553(b) and (c).

[20] 5 U.S.C. 553(b)(3)(A).

[21] 5 U.S.C. 553(b)(3)(B).

[22] *See* 5 U.S.C. 601(2) (for purposes of a Regulatory Flexibility Act analysis, the term ''rule'' means any rule for which the agency publishes a general notice of proposed rulemaking) and 5 U.S.C. 804(3)(C) (for purposes of Congressional review of agency rulemaking, the term ''rule'' does not include any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties).

[23] 5 U.S.C. 553(d)(3).

[24] *Id.*

[25] 5 U.S.C. 553(d)(1).

[26] 44 U.S.C. 3501 *et seq.*

[27] Section 3(f) of the Exchange Act, Section 2(b) of the Securities Act, and Section 2(c) of the Investment Company Act state that when engaging in rulemaking that requires us to consider or determine whether an action is necessary or appropriate in (or, with respect to the Investment Company Act, consistent with) the public interest, we must consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. Additionally, Section 23(a)(2) of the Exchange Act requires us, when making rules or regulations under the Exchange Act, to consider, among other matters, the impact that any such rule or regulation would have on competition and states that the Commission shall not adopt any such rule or regulation which would impose a burden on competition that is not necessary or appropriate in furtherance of the Exchange Act.

[28] 17 CFR 230.101.

impossible for a signatory to deny signing the document.[29] Moreover, digital signature systems can be deployed on a broad range of computing platforms,[30] and are widely accessible at low cost.

Technological developments have also increased the efficiency of electronic communication relative to reliance on the mail. Remote work, as opposed to work on a business's premises, has increased for management, professional, and related occupations.[31] These changes have been facilitated by developments in technology and communications infrastructure,[32] as a greater volume of business communication now occurs electronically, rather than through paper, workers in these occupations have adapted to electronic communications. Further, remote work has increased substantially in recent months due to the COVID–19 pandemic. Survey evidence collected during the pandemic shows that a substantial proportion of the U.S. labor force now works from home full time.[33] At the same time, measures related to COVID–19 have, at the margin, increased the time associated with printing and mailing, and in some cases have increased the risk of delay.[34] In response to lengthier or less certain printing and mailing times, filers may incur additional costs by hastening internal processes to meet external deadlines.

We expect the amendments to Rule 302(b), and the related amendments to certain rules and forms under the Securities Act, the Exchange Act, and the Investment Company Act will result in cost savings for those filers whose signatories sign an authentication document by using an electronic signature. Filers who choose this option would no longer be required to have a signatory manually sign a signature page or other document and convey that document to the filer for each typed signature they provide in each filing that is made. Thus filers and signatories would not incur related costs of printing or mailing such a document in connection with each typed signature and may experience cost reductions to the extent that retaining electronic authentication documents is less costly than retaining manual authentication documents. It is difficult to quantify cost savings per filing as they would depend on the nature of the filing and the circumstances of the individual signatories.[35] Further, cost savings per filer would depend on the number and nature of filings each filer must make.[36] To the extent that the amendments make filers' compliance programs more efficient and less expensive, filers may be able to reallocate resources otherwise used for printing or mailing authentication documents to more productive uses. Filers may experience greater cost savings to the extent they choose to incorporate processes for electronic signatures in the design of their overall compliance programs and such processes are lower cost than their manual equivalents.

We do not expect the amendments to Rule 302(b) to impose substantial additional costs on filers because filers will be permitted to continue to use manually signed authentication documents and existing policies and procedures if they choose to do so. Because the electronic signing process for authentication documents would be optional, we expect that filers would avail themselves of this option only to the extent that the potential benefits justified any associated costs.

Filers that choose to avail themselves of the ability to use electronic signatures in authentication documents may need to update their compliance systems to ensure that a signatory manually signs a document attesting that the signatory agrees that the use of an electronic signature in any authentication document constitutes the legal equivalent of such individual's manual signature, before first utilizing an electronic signature to sign an authentication document. Further, filers must retain this initial signature authentication document for a minimum period of seven years after the date of the most recent electronically signed authentication document, and must furnish a copy of it upon request to the Commission or its staff. However, we generally expect these one-time costs to be relatively low, and once such a filer has updated its systems, we do not believe these substantive requirements will result in additional on-going costs because producing and retaining authentication documents are existing requirements under Rule 302(b). Additionally, such filers may incur costs associated with compliance with the electronic signing process requirements prescribed in the EDGAR Filer Manual. These costs include initial costs related to identifying and acquiring software capable of producing electronic signatures that meet the updated process requirements and likely also include annual fees associated with ongoing use of electronic signature software.

We do not expect the amendments to have meaningful effects on competition or capital formation. As noted above, the amendments may improve efficiency, to the extent that they permit filers to lower the costs associated with complying with the amended rules. The amendments could reduce the variable cost (cost per filing) associated with meeting Commission filing requirements. If meeting Commission filing requirements involves high fixed costs then this reduction in variable costs could reduce the average cost of filing for high-volume filers more than for low-volume filers. Similarly, a filer's printing and mailing costs under the baseline depend both on the number of signatures required for its filings and the need for mailing manual signature pages to a central location. Thus, filers that have a larger number of signatories, or have signatories that are more geographically dispersed, likely would experience greater cost savings than filers with fewer or less-dispersed signatories.

Finally, we considered alternative ways of permitting the use of electronic

[29] *See* William Kuechler & Fritz H. Grupe, *Digital Signatures: A Business View,* 19(4) Info. Sys. Mgmt. 19 (2003).

[30] *Id.*

[31] *See* Rachel M. Krantz-Kent, *Where did workers perform their jobs in the early 21st century?,* U.S. Bureau of Lab. Stat.: Monthly Lab. Rev. (July 2019), *available at: https://doi.org/10.21916/mlr.2019.16* (last accessed October 22, 2020).

[32] *Id.*

[33] *See* Erik Brynjolfsson et al., *COVID–19 and remote work: an early look at US data* (Nat'l Bureau of Economic Research, No. w27344, 2020). *See also* May Wong, *Stanford Research Provides a Snapshot of a New Working-From-Home Economy* (June 29, 2020), *available at: https://news.stanford.edu/2020/06/29/snapshot-new-working-home-economy/* (last accessed Oct. 13, 2020).

[34] For example, The U.S. Postal Service announced that certain two-day and three-day service commitments were extended to three days and four days, respectively, and suspended services or service guarantees for international shipments. Private carriers similarly suspended guarantees. *See e.g., USPS® Coronavirus Updates: Expected Delivery Changes,* USPS: FAQ (Apr. 17, 2020) *available at: https://faq.usps.com/s/article/USPS-Coronavirus-Updates-Expected-Delivery-Changes* (last accessed Oct. 10, 2020).

[35] Analysis of electronic filers in EDGAR in 2019 demonstrates substantial variation in the number of signatories per filing. For example, we estimate 99.0% of 6,660 Form 10–K filings included more than one signatory in 2019, while only 1.6% of 14,884 Form 497 filings included more than one signatory in 2019. Staff were able to identify approximately 105,000 electronic filings with multiple signatories in 2019 by searching for signature tags in all electronic filings. Although this method may fail to identify certain filings with multiple signatories that do not tag individual signatures, this sample serves to demonstrate the degree of variability in the number of signatories across form types.

[36] Analysis of electronic filers in EDGAR in 2019 demonstrates a high degree in variation in the number of filings per filer. Staff estimate that the median number of filings per filer across the full sample of filers was two, however, the 25 filers with the largest number of filings in 2019 each submitted more than 850 filings.

signatures in authentication documents. The Commission could have chosen not to adopt a requirement to create or retain an initial electronic signature authentication document. Such an alternative would have increased cost savings for filers, but could have undermined the evidentiary value of the authentication document. The Commission also considered longer or shorter retention periods for authentication documents. Longer (shorter) retention periods could increase (decrease) the costs associated with storing authentication documents, while potentially increasing (decreasing) the evidentiary benefits of such documents.

V. Statutory Authority

The amendments contained in this release are being adopted under the authority in Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[37] Sections 3, 12, 13, 14, 15, 15B, 23, and 35A of the Securities Exchange Act of 1934,[38] Section 319 of the Trust Indenture Act of 1939,[39] and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[40]

List of Subjects

17 CFR Part 230

Investment companies, Reporting and recordkeeping requirements, Securities.

17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

17 CFR Part 240

Brokers, Fraud, Reporting and recordkeeping requirements, Securities.

17 CFR Part 249

Brokers, Reporting and recordkeeping requirements, Securities.

17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of the Amendments

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

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 1. The authority citation for part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78*l,* 78m, 78n, 78*o,* 78*o*–7 note, 78t, 78w, 78*ll*(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

Sections 230.400 to 230.499 issued under secs. 6, 8, 10, 19, 48 Stat. 78, 79, 81, and 85, as amended (15 U.S.C. 77f, 77h, 77j, and 77s).

* * * * *

■ 2. Amend § 230.402 by revising paragraph (e) to read as follows:

§ 230.402 Number of copies; binding; signatures.

* * * * *

* * * * *

(e) *Signatures.* Where the Act or the rules thereunder, including paragraphs (a) and (c) of this section, require a document filed with or furnished to the Commission to be signed, such document shall be manually signed, or signed using either typed signatures or duplicated or facsimile versions of manual signatures. Where typed, duplicated, or facsimile signatures are used, each signatory to the filing shall manually or electronically sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in the filing (''authentication document''). Such authentication document shall be executed before or at the time the filing is made and shall be retained by the registrant for a period of five years. The requirements set forth in § 232.302(b) must be met with regards to the use of an electronically signed authentication document pursuant to this paragraph (e). Upon request, the registrant shall furnish to the Commission or its staff a copy of any or all documents retained pursuant to this section.

■ 3. Amend § 230.471 by revising paragraph (b) to read as follows:

§ 230.471 Signatures to amendments.

* * * * *

(b) Where the Act or the rules thereunder require a document filed with or furnished to the Commission to be signed, such document shall be manually signed, or signed using either typed signatures or duplicated or facsimile versions of manual signatures. Where typed, duplicated, or facsimile signatures are used, each signatory to the filing shall manually or electronically sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in the filing (''authentication document''). Such authentication document shall be executed before or at the time the filing is made and shall be retained by the registrant for a period of five years. The requirements set forth in § 232.302(b) must be met with regards to the use of an electronically signed authentication document pursuant to this paragraph (b). Upon request, the registrant shall furnish to the Commission or its staff a copy of any or all documents retained pursuant to this section.

PART 232 REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 4. The authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78*o*(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

Section 232.302 is also issued under secs. 3(a) and 302, Pub. L. No. 107–204, 116 Stat. 745.

■ 5. Revise § 232.301 to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: ''General Information,'' Version 35 (January 2020). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 55 (November 2020). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available at *https://www.sec.gov/info/edgar/edmanuals.htm.* The EDGAR Filer Manual is also 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. You can also inspect the document 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: *https://*

[37] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[38] 15 U.S.C. 78c, 78*l,* 78m, 78n, 78o, 78o–4, 78w, and 78*ll.*

[39] 15 U.S.C. 77sss.

[40] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

www.archives.gov/federal-register/cfr/ibrlocations.html.

■ 6. Amend § 232.302 by revising paragraphs (a) and (b) to read as follows:

§ 232.302 Signatures.

(a) Required signatures to, or within, any electronic submission (including, without limitation, signatories within the certifications required by §§ 240.13a–14, 240.15d–14, and 270.30a–2 of this chapter) must be in typed form rather than manual format. Signatures in an HTML document that are not required may, but are not required to, be presented in an HTML graphic or image file within the electronic filing, in compliance with the formatting requirements of the EDGAR Filer Manual. When used in connection with an electronic filing, the term ''signature'' means a computer representation of any symbol or series of symbols comprising a name executed, adopted, or authorized as a signature. Signatures are not required in unofficial PDF copies submitted in accordance with § 232.104.

(b)(1) Each signatory to an electronic filing (including, without limitation, each signatory to the certifications required by §§ 240.13a–14, 240.15d–14 and 270.30a–2 of this chapter) shall manually or electronically sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in typed form within the electronic filing (''authentication document''). Such authentication document shall be executed before or at the time the electronic filing is made and shall be retained by the filer for a period of five years. An electronically signed authentication document pursuant to this paragraph (b)(1) must meet the requirements set forth in the EDGAR Filer Manual.

(2) Before a signatory may electronically sign an authentication document pursuant to paragraph (b)(1) of this section, such signatory must manually sign a document attesting that, when using electronic signatures for purposes of paragraph (b)(1) of this section, the signatory agrees that the use of such electronic signature constitutes the legal equivalent of such individual's manual signature for purposes of authenticating the signature to any filing for which it is provided. An electronic filer must retain this document for as long as the signatory may use an electronic signature to satisfy the requirements of paragraph (b)(1) of this section and for a minimum period of seven years after the date of the most recent electronically signed authentication document.

(3) Upon request, an electronic filer shall furnish to the Commission or its staff a copy of any or all documents retained pursuant to this section. A manually signed document under paragraph (b)(1) or (2) of this section, including an initial electronic signature authentication document or a manually signed authentication document, may be retained and stored via electronic means.

* * * * *

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

■ 7. 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, 78dd, 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, secs. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

Sections 240.12b–1 to 240.12b–36 also issued under secs. 3, 12, 13, 15, 48 Stat. 892, as amended, 894, 895, as amended; 15 U.S.C. 78c, 78*l,* 78m, and 78*o.*

* * * * *

Section 240.14d–1 is also issued under 15 U.S.C. 77g, 77j, 77s(a), 77ttt(a), 80a–37.

* * * * *

■ 8. Amend § 240.12b–11 by revising paragraph (d) to read as follows:

§ 240.12b–11 Number of copies; signatures; binding.

* * * * *

(d) *Signatures.* Where the Act or the rules, forms, reports or schedules thereunder, including paragraph (b) of this section, require a document filed with or furnished to the Commission to be signed, such document shall be manually signed, or signed using either typed signatures or duplicated or facsimile versions of manual signatures. Where typed, duplicated, or facsimile signatures are used, each signatory to the filing shall manually or electronically sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in the filing (''authentication document''). Such authentication document shall be executed before or at the time the filing is made and shall be retained by the filer for a period of five years. The requirements set forth in § 232.302(b) must be met with regards to the use of an electronically signed authentication document pursuant to this paragraph (d). Upon request, the filer shall furnish to the Commission or its staff a copy of any or all documents retained pursuant to this section.

■ 9. Amend § 240.14d–1 by revising paragraph (h) to read as follows:

§ 240.14d–1 Scope of and definitions applicable to Regulations 14D and 14E.

* * * * *

(h) *Signatures.* Where the Act or the rules, forms, reports or schedules thereunder require a document filed with or furnished to the Commission to be signed, such document shall be manually signed, or signed using either typed signatures or duplicated or facsimile versions of manual signatures. Where typed, duplicated, or facsimile signatures are used, each signatory to the filing shall manually or electronically sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in the filing (''authentication document''). Such authentication document shall be executed before or at the time the filing is made and shall be retained by the filer for a period of five years. The requirements set forth in § 232.302(b) must be met with regards to the use of an electronically signed authentication document pursuant to this paragraph (h). Upon request, the filer shall furnish to the Commission or its staff a copy of any or all documents retained pursuant to this section.

■ 10. Amend § 240.15Fb1–1 by revising paragraphs (b) and (d) to read as follows:

§ 240.15Fb1–1 Signatures.

* * * * *

(b) Each signatory to an electronic filing (including, without limitation, each signatory to the forms and certifications required by §§ 240.15Fb2–1, 240.15Fb2–4, and 240.15Fb6–2) shall manually or electronically sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in typed form within the electronic filing (''authentication document''). Such authentication document shall be executed before or at the time the electronic filing is made. The requirements set forth in § 232.302(b) must be met with regards to the use of an electronically signed authentication document pursuant to this paragraph (b). Upon request, the security-based swap dealer or major security-based swap participant shall furnish to the Commission or its staff a

copy of any or all documents retained pursuant to this paragraph (b).

* * * * *

(d) Each manually or electronically signed signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in typed form within the electronic filing (''authentication document'')—

(1) On Schedule F to Form SBSE (§ 249.1600 of this chapter), SBSE–A (§ 249.1600a of this chapter), or SBSE–BD (§ 249.1600b of this chapter), as appropriate, shall be retained by the filer until at least three years after the form or certification has been replaced or is no longer effective;

(2) On Form SBSE–C (§ 249.1600c of this chapter) shall be retained by the filer until at least three years after the Form was filed with the Commission.

■ 11. Amend § 240.16a–3 by revising paragraph (i) to read as follows:

§ 240.16a–3 Reporting transactions and holdings.

* * * * *

(i) *Signatures.* Where Section 16 of the Act, or the rules or forms thereunder, require a document filed with or furnished to the Commission to be signed, such document shall be manually signed, or signed using either typed signatures or duplicated or facsimile versions of manual signatures. Where typed, duplicated, or facsimile signatures are used, each signatory to the filing shall manually or electronically sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in the filing (''authentication document''). Such authentication document shall be executed before or at the time the filing is made and shall be retained by the filer for a period of five years. The requirements set forth in § 232.302(b) must be met with regards to the use of an electronically signed authentication document pursuant to this paragraph (i). Upon request, the filer shall furnish to the Commission or its staff a copy of any or all documents retained pursuant to this section.

* * * * *

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 12. The general authority citation for part 249 continues to read as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.;* 12 U.S.C. 5461 *et seq.;* 18 U.S.C. 1350; Sec. 953(b), Pub. L. 111–203, 124 Stat. 1904; Sec. 102(a)(3), Pub. L. 112–106, 126 Stat. 309 (2012); Sec. 107, Pub. L. 112–106, 126 Stat. 313 (2012), and Sec. 72001, Pub. L. 114–94, 129 Stat. 1312 (2015), unless otherwise noted.

* * * * *

■ 13. Amend Form CB (referenced in § 249.480) by amending General Instruction II.B to read as follows:

Note: The text of Form CB does not, and this amendment will not, appear in the Code of Federal Regulations.

United States

Securities and Exchange Commission

Washington, DC 20549

Form CB

* * * * *

B. When submitting the Form CB in electronic format, the persons specified in Part IV must provide signatures in accordance with Regulation S–T Rule 302 (17 CFR 232.302). When submitting the Form CB in paper, the persons specified in Part IV must sign the original and at least one copy of the Form and any amendments. You must conform any unsigned copies. The specified persons may provide typed or facsimile signatures in accordance with Securities Act Rule 402(e) (17 CFR 230.402(e)) or Exchange Act Rule 12b–11(d) (17 CFR 240.12b–11(d)) as long as the filer retains copies of signatures manually or electronically signed by each of the specified persons for five years. The requirements set forth in Regulation S–T Rule 302(b) (17 CFR 232.302(b)) must be met with regards to the use of an electronically signed signature page.

* * * * *

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

■ 14. The authority citation for part 270 continues to read, in part, as follows:

Authority: 15 U.S.C. 80a–1 *et seq.,* 80a–34(d), 80a–37, 80a–39, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

* * * * *

Section 270.8b–11 is also issued under 15 U.S.C. 77s, 80a–8, and 80a–37.

* * * * *

■ 15. Amend § 270.8b–11 by revising paragraph (e) to read as follows:

§ 270.8b–11 Number of copies; signatures; binding.

* * * * *

(e) *Signatures.* Where the Act or the rules thereunder, including paragraph (c) of this section, require a document filed with or furnished to the Commission to be signed, the document should be manually signed, or signed using either typed signatures or duplicated or facsimile versions of manual signatures. When typed, duplicated, or facsimile signatures are used, each signatory to the filing shall manually or electronically sign a signature page or other document authenticating, acknowledging, or otherwise adopting his or her signature that appears in the filing (''authentication document''). Execute each such authentication document before or at the time the filing is made and retain for a period of five years. The requirements set forth in § 232.302(b) must be met with regards to the use of an electronically signed authentication document pursuant to this paragraph (e). Upon request, the registrant shall furnish to the Commission or its staff a copy of any or all documents retained pursuant to this section.

By the Commission.

Dated: November 17, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–26166 Filed 12–3–20; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 214

[Docket No. FR–6215–I–02]

RIN 2502–ZA34

Housing Counseling Program: Revision of the Certification Timeline

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This final rule follows HUD's interim final rule (the interim rule) published on August 5, 2020. The interim rule extended the deadline by which participating agencies and counselors must comply with certification requirements in HUD's Housing Counseling Program from August 1, 2020 to August 1, 2021. The reason for the extension is that due to the COVID–19 national emergency, a large number of housing counselors would have been unable to get certified by the end of the grace period, resulting in a loss of Federal funding for some HUD-approved housing counseling agencies and loss of the ability to provide counseling that is required or provided in numerous HUD programs. HUD considered public comment on the interim rule. This rule makes the interim rule a final rule, without change.

DATES: *Effective date:* The August interim rule (85 FR 47300) extending the August 1, 2020 counseling certification deadline is confirmed as final on December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Lorraine Griscavage-Frisbee at Office of Housing Counseling, Office of Housing, Department of Housing and Urban Development, 302 Carson Street, Las Vegas, Nevada 89101, telephone number 702–366–2160 (this is not a toll-free number). Persons with hearing or speech challenges may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339. Questions can also be addressed to Lorraine Griscavage-Frisbee, Office of Housing Counseling, at *housing.counseling@hud.gov.* Please include ''Housing Counseling Program: Date Housing Counseling Agencies Must Comply with Certification Requirements'' in the subject line of the email.

I. Background

Section 106 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701x) (Section 106) was amended by Subtitle D of title XIV of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203, 124 Stat. 1376, approved July 21, 2010) to strengthen and improve the effectiveness of housing counseling that is required under or provided in connection with HUD programs (Section 106 amendments). The Section 106 amendments require that individuals providing housing counseling required under or provided in connection with HUD programs be certified by taking and passing an examination administered by HUD's Office of Housing Counseling (12 U.S.C. 1701x(e)). On December 14, 2016, HUD published a final rule implementing the Section 106 certification requirements, including the requirement that housing counseling that is required by or in connection with HUD programs may only be provided by HUD certified housing counselors working for HUD-approved housing counseling agencies (HCAs) that are approved to provide such housing counseling by HUD's Office of Housing Counseling. *See* 81 FR 90632. The 2016 final rule codified the grace period at 24 CFR 214.103(n)(4), which provides that ''[p]articipating agencies and housing counselors must be in compliance with requirements of paragraph (n) of this section by 36 months after HUD commences the administration of the certification examination by publication in the **Federal Register**.'' On May 31, 2017, HUD published a notice announcing the availability of the certification examination beginning August 1, 2017, and providing the deadline of August 1, 2020, within which all housing counselors and HCAs must satisfy the certification requirements in the final rule. *See* 82 FR 24988.

On March 13, 2020, the President declared the Coronavirus Disease 2019 (COVID–19) outbreak a national emergency, effective March 1, 2020. HUD housing counselor certification testing centers started to close in mid-March 2020, and by mid-April 2020, all 462 testing centers had closed. In addition, all 35 HUD in-person place-based housing counselor certification trainings originally scheduled were cancelled, severely impacting the ability of all counselors and counseling agencies to be certified by the deadline. Accordingly, on August 5, 2020, HUD published an interim rule amending 24 CFR 214.103(n)(4) to announce the new compliance date as August 1, 2021 (*See* 85 FR 47300).

II. The Public Comments

The public comment period for the interim rule closed on September 4, 2021. HUD received one comment. This comment was generally supportive of the rule and stated that HUD should consider offering resources and testing beyond English and Spanish. Specifically, the comment read: ''Housing Counselors who speak and serve populations who speak a language other than English or Spanish are finding it difficult to achieve certification without appropriate materials. As such, many culturally specific organizations could end up without a certified Counselor.''

HUD Response. The interim rule amended only 24 CFR 214.103(n)(4), leaving the remainder of the rule in place. The rule currently provides, at § 214.103(g)(3), that counseling agencies ''must have housing counselor(s) who are fluent in the language of the clients they serve, or the housing counseling agency must use the services of an interpreter, or the agency must refer the client to another agency that can meet the client's needs.'' While HUD agrees that counseling agencies should serve clients who may speak languages other than English or Spanish, HUD finds that the current regulation is adequate in this regard. Furthermore, the interim rule concerned a specific issue regarding a date by which counselors would have to be certified, and other aspects of the housing counseling regulations are outside the scope of the interim rule. Therefore, HUD is not making a change regarding its language policy.

III. This Final Rule

This final rule adopts the interim rule, published at 85 FR 47300 (August 5, 2020), without change.

IV. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome,'' and to modify, streamline, expand, or repeal them in accordance with what has been learned. Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. This final rule was not determined to be a ''significant regulatory action'' as defined in section 3(f) of the Executive order, and is not expected to impose any burdens or costs, for the reasons stated in the interim rule at 85 FR 47303 (August 5, 2020).

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This final rule will not impose any federal mandates on any state, local, or tribal governments or the private sector within the meaning of UMRA.

Environmental Review

This final rule does not (i) Direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction; or (ii) Establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this final rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Impact on Small Entities

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601, *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This final rule allows housing counseling agencies to continue to operate as they currently do during the COVID–19 emergency. Therefore, the undersigned certifies that this final rule will not have a significant impact on a substantial number of small entities.

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 the rule 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 nor preempt state law within the meaning of the Executive order.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance (CFDA) Program number for the Housing Counseling Program is 14.169.

List of Subjects in 24 CFR Part 214

Administrative practice and procedure; Loan program-housing and community development; Organization and functions (government agencies); Reporting and recordkeeping requirements.

PART 214—HOUSING COUNSELING PROGRAM

■ Accordingly, for the reasons stated in the preamble, the interim rule amending 24 CFR part 214 that was published at 85 FR 47300 (August 5, 2020) is adopted without change.

Dana T. Wade,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2020–26194 Filed 12–3–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2020–0540]

RIN 1625–AA00

Safety Zone; Oakland Ship-to-Shore Crane Arrival, San Francisco Bay, Oakland, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the San Francisco Bay during the transit of the M/V ZHEN HUA 35, scheduled to arrive between December 6, 2020 and December 20, 2020. This safety zone is necessary to protect personnel, vessels, and the marine environment from heavy equipment which will be extending more than 200 feet over the water from the vessel. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port San Francisco or a designated representative.

DATES: This rule is effective from 12:01 a.m. on December 6, 2020 until 11:59 p.m. on December 20, 2020, or as announced via Broadcast Notice to Mariners.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0540 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Jennae Cotton, Waterways Management, U.S. Coast Guard; telephone (415) 399–3585, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port San Francisco
DHS Department of Homeland Security
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking with respect to this rule because it is impracticable. The Coast Guard did not receive final details for this event until November 20, 2020. The Coast Guard must establish this safety zone by December 6, 2020 and lacks sufficient time to provide a reasonable comment period and consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. It is contrary to the public interest to delay the effective date of this rule because we need to have the safety zone in place to protect vessels and persons from the dangers associated with the crane arms extending over the water from the M/V ZHEN HUA 35 between December 6, 2020 and December 20, 2020 while the vessel is shoreward of the line drawn between San Francisco Main Ship Channel Lighted Bell Buoy 7 and San Francisco Main Ship Channel Lighted Whistle Buoy 8 until the vessel arrives at Berth 57 in Oakland, CA.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco has determined that potential hazards associated with the transit of the M/V ZHEN HUA 35 between December 6, 2020 and December 20, 2020, will be a safety concern for anyone within a 500-foot radius of the vessel during its transit to Oakland, Berth 57, while the vessel is within the San Francisco Bay and areas shoreward of the line drawn between San Francisco Main Ship Channel Lighted Bell Buoy 7 and San Francisco Main Ship Channel Lighted Whistle Buoy 8 (LLNR 4190 & 4195) in positions 37°46.9′ N, 122°35.4′ W and 37°46.5′ N, 122°35.2′ W, respectively. For this reason, a safety zone is needed to protect personnel, vessels, and the marine environment in the navigable waters around the M/V ZHEN HUA 35 during its transit to Berth 57 at the Oakland International Container Terminal in Oakland, CA.

IV. Discussion of the Rule

This rule establishes a safety zone from 12:01 a.m. on December 6, 2020 until 11:59 p.m. on December 20, 2020, during the inbound transit of the M/V ZHEN HUA 35. While the M/V ZHEN HUA 35 is within the San Francisco Bay and areas shoreward of the line drawn between San Francisco Main Ship Channel Lighted Bell Buoy 7 and San Francisco Main Ship Channel Lighted Whistle Buoy 8 (LLNR 4190 & 4195) in positions 37°46.9′ N, 122°35.4′ W and 37°46.5′ N, 122°35.2′ W, respectively, the safety zone will encompass the navigable waters around and under the vessel, from surface to bottom, within a circle formed by connecting all points 500 feet out from the vessel. The safety zone is needed to protect personnel, mariners, and vessels from hazards associated with ship-to-shore crane arms which will extend more than 200 feet out from the transiting vessel. This loading configuration is necessary in order for the vessel to pass safely under the Golden Gate Bridge and the San Francisco-Oakland Bay Bridge.

The M/V ZHEN HUA 35 will make a temporary stop in Anchorage 9 during its transit to the Oakland International Container Terminal. The vessel will stop temporarily for the crew to make adjustments to the cargo so the vessel can safely moor at Berth 57 in Oakland, CA. The cargo adjustments will include raising three ship-to-shore crane arms to an upright position which will facilitate mooring.

The effect of the safety zone is to restrict navigation in the vicinity of the M/V ZHEN HUA 35. Except for persons or vessels authorized by the COTP or the COTP's designated representative, no person or vessel may enter or remain in the restricted area. ''Designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone. This regulation is needed to keep vessels away from the immediate vicinity of the M/V ZHEN HUA 35 to ensure the safety of mariners and transiting vessels.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. This safety zone impacts a 500-foot-radius area of the San Francisco Bay in San Francisco, CA for a limited duration. While the safety zone encompasses a two week period to account for uncertain transit delays of the M/V ZHEN HUA 35, the safety zone will only be enforced for the duration of the vessel's inbound transit, which is expected to last less than 24 hours. Vessels desiring to transit through the safety zone may do so upon express permission from the COTP or the COTP's designated representative.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of

$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and U.S. Coast Guard Environmental Planning Policy, COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone which prevents entry to a 500-foot radius area of the San Francisco Bay for a limited period of time during a vessel's inbound transit. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of Department of Homeland Security Directive 023–01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T11–035 to read as follows:

§ 165.T11–035 Safety Zone; Oakland Ship-to-Shore Crane Arrival, San Francisco Bay, Oakland, CA

(a) *Location.* The following area is a safety zone: all navigable waters of the San Francisco Bay, from surface to bottom, within a circle formed by connecting all points 500 feet out from the vessel, M/V ZHEN HUA 35, during the vessel's inbound transit from a line drawn between San Francisco Main Ship Channel Lighted Bell Buoy 7 and San Francisco Main Ship Channel Lighted Whistle Buoy 8 (LLNR 4190 & 4195) in positions 37°46.9′ N, 122°35.4′ W (NAD 83) and 37°46.5′ N, 122°35.2′ W (NAD 83), respectively, to Berth 57 at the Oakland International Container Terminal in Oakland, CA.

(b) *Definitions.* As used in this section, ''designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart B of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF–23A or through the 24-hour Command Center at telephone (415) 399–3547.

(d) *Enforcement period.* This section will be enforced between 12:01 a.m. on December 6, 2020 until 11:59 p.m. on December 20, 2020 during the inbound transit of the M/V ZHEN HUA 35, or as announced via Broadcast Notice to Mariners.

(e) *Information broadcasts.* The COTP or the COTP's designated representative will notify the maritime community of periods during which this zone will be enforced, in accordance with 33 CFR 165.7.

Howard H. Wright,

Captain, U.S. Coast Guard, Alternate Captain of the Port, San Francisco.

[FR Doc. 2020–26686 Filed 12–3–20; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 501

Authorization To Manufacture and Distribute Postage Evidencing Systems

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: In this final rule, the Postal Service withdraws all authorizations to distribute (decertifies) Postage Evidencing Systems (PES) that are not producing compliant Intelligent Mail Indicia (IMI) on June 30, 2024. IMI compliant PES are defined in the IMI Performance Criteria (IMI–PC) and produce only IMI-Minimum (IMI–MIN), IMI-Standard (IMI–STD), and IMI-Maximum (IMI–MAX) indicia constructs (as stated in the IMI–PC). All PES that are not IMI–PC compliant, also referenced as Phase VI–IBI and Phase VII–PC Postage (collectively Phase VI and Phase VII PES), will become decertified Postage Evidencing Systems on June 30, 2024. The decertified Postage Evidencing Systems must be withdrawn from service by December 31, 2024. As of December 31, 2024, the decertified PES must be marked inactive in the USPS PES management systems, including in the National Meter Accounting and Tracking System (NMATS). Postage indicia printed by Decertified PES will no longer be considered valid postage for use or refunds after June 30, 2025.

DATES: This final rule is effective December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Ezana Dessie, Principal Business Systems Analyst, *Ezana.Dessie@usps.gov,* (202) 268–5686.

SUPPLEMENTARY INFORMATION: In response to a notice of proposed rulemaking (85 FR 30671, May 20, 2020) to decertify and withdraw all non-Intelligent Mail Indicia (IMI) compliant Postage Evidencing Systems (PES) by June 30, 2024, the Postal Service received industry comments and feedback. The comments and feedback can be grouped into three areas: (I) Requests for an extension on the proposed dates for both the withdrawal of Decertified PES and the decertification of non IMI-postage indicia; (II) provision of more specificity on IMI–PC compliance and clarification on several items related to the decertification; and (III) additional clarification on the support the Postal Service will provide to the PES providers on the PES migration (from Information Based Indicia Program

(IBIP) to IMI–PC). We will address all three areas in turn below.

I. Requests for an extension on the proposed dates for both the withdrawal of Decertified PES and the decertification of non-IMI postage indicia.

The Postal Service has taken into consideration the concerns of the industry and is extending the dates for withdrawal of decertified PES and decertified indicia. The new withdrawal date will be December 31, 2024; the last date non-IMI indicia will be accepted for use as postage or for refunds will be June 30, 2025. Some commenters argued that changes to the IMI–PC before June 30, 2024 should extend the decertification date. The Postal Service will strive to minimize the number of changes it requires, but some changes will be inevitable and will not extend the timeline.

II. Provision of more specificity on IMI–PC compliance and clarification on several items related to the decertification.

Like any other institution, the Postal Service needs accurate, complete, and timely data to operate effectively; the IMI–PC supports these key business objectives for the Postal Service. The IMI–PC requires the PES providers to submit more detailed transaction data, with increased transparency and frequency; it also employs higher security specifications which address the rising security threats and challenges. IMI–PC enables the USPS to provide more detailed corporate reporting, more accurately price shipping/mailing products, attain operational efficiency by automating many functions (including postage refunds), improve the USPS Federal Regulatory compliance, and better secure Postal Service and customer data. Finally, the IMI–PC provides the USPS a better platform to bring improvements and updates to the USPS PES related products and services.

Phase VI and Phase VII PES no longer meet the USPS PES requirements adequately. Commercial Payment has shared with each provider a list of Phase VI and Phase VII PES that are not IMI–PC compliant. A PES is IMI–PC compliant when conforming to IMI–PC specifications and all other current PES related guidelines, regulations, and technical requirements; this includes the rules and regulations in the Domestic Mail Manual, International Mail Manual, Publication 199, Notice 123, Code of Federal Regulations, and having a Postal Security Device (PSD) that has a valid Federal Information Processing Standards (FIPS) certificate at the time of authorization. The decertification and withdrawal of the Phase VI and Phase VII PES will allow for the full implementation of Phase VIII–IMI PES, in which both PC Postage and physical PES are validated under the current edition of the IMI–PC.

In keeping with the June 30, 2024 decertification date and the December 31, 2024 withdrawal date, the providers must stop leasing non-IMI–PC compliant PES for lengths extending beyond the withdrawal date. Postage indicia printed by Decertified PES will not be considered valid postage after June 30, 2025; also, refund requests for all unused postage indicia need to be completed before this date. As the withdrawal date for PES approaches, the providers must coordinate with Commercial Payment (or its successor) to invalidate and remove the non-IMI–PC compliant PES from USPS PES product-service-line, in accordance with IMI–PC PES withdrawal guidelines.

In rare and select cases, for unique service/business reasons that the Postal Service deems appropriate, PES providers may request a waiver to operate non-IMI–PC compliant PES beyond the December 31, 2024 withdrawal date. The waiver request form can be obtained from Commercial Payment. Any waiver granted will be in writing from Commercial Payment, or its successor.

III. Additional clarification on the support the Postal Service will provide to the PES providers on the PES migration (from Information Based Indicia Program (IBIP) to IMI–PC).

The updated withdrawal date (December 31, 2024) is based on the feedback and comments from the PES industry, the impact of the COVID–19 pandemic on the mailing and shipping industry, current market needs, and the USPS long-term PES product support/management strategies. The USPS believes the updated withdrawal date allows the PES providers to execute the decertification and withdrawal process and complete the IBIP to IMI–PC transition with minimal impact to our customers. The USPS is committed to supporting the providers in the decertification and withdrawal process to minimize the impact of the transition to our PES customers. To this end, the USPS will provide the providers with three support tools for communication with their end customers: (1) A publication on the importance/value of IMI–PC for USPS (this will be available on PostalPro for the providers to utilize for their customer communications); (2) a license agreement for use of an IMI logo and wordmark to support the providers' PES transition and IMI PES marketing work; and (3) USPS-led customer outreach in collaboration with the providers, when the Postal Service deems it necessary.

List of Subjects in 39 CFR Part 501

Administrative practice and procedure, Postal Service.

For the reasons stated in the preamble, the Postal Service amends 39 CFR part 501 as follows:

PART 501—[AMENDED]

■ 1. The authority citation for part 501 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 410, 2601, 2605; Inspector General Act of 1978, as amended (Pub. L. 95–452, as amended); 5 U.S.C. App. 3.

■ 2. Amend § 501.7 by revising paragraph (c) introductory text to read as follows:

§ 501.7 Postage Evidencing System requirements.

* * * * *

(c) The provider must ensure that any matter printed by a Postage Evidencing System, whether within the boundaries of the indicia or outside the clear zone as defined in DMM 604.4.0 and the Intelligent Mail Indicia Performance Criteria (IMI–PC), is:

* * * * *

■ 3. Amend § 501.17 by adding paragraph (f) to read as follows:

§ 501.17 Decertified Postage Evidencing Systems.

* * * * *

(f) Postage Evidencing Systems that do not comply with the then current Intelligent Mail Indicia Performance Criteria will be Decertified Postage Evidencing Systems on June 30, 2024. The withdrawal date for those systems will be December 31, 2024.

■ 4. Amend § 501.20 by revising paragraph (b) to read as follows:

§ 501.20 Discontinued Postage Evidencing Indicia.

* * * * *

(b) Effective December 31, 2024 all Postage Evidencing Systems that do not to produce Intelligent Mail Indicia (IMI) for evidence of pre-paid postage must be withdrawn from service. Non-IMI indicia, which are not compliant with the then-current version of the IMI–PC, will be decertified and may not be used as a valid form of postage evidence. These decertified indicia may not be

recognized as valid postage for use or refunds, after June 20, 2025.

Ruth Stevenson,

Attorney, Federal Compliance.

[FR Doc. 2020–26129 Filed 12–3–20; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0955–AA02

Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency; Correction

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: This document corrects typographical errors found in the interim final rule entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' that was published in the **Federal Register** on November 4, 2020.

DATES: The corrections in this document are effective on December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

I. Background

This document corrects typographical errors found in the interim final rule entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency,'' (**Federal Register** document 2020–24376) (85 FR 70064), that was published in the **Federal Register** on November 4, 2020. We summarize and correct these errors in the ''Summary of Errors'' and ''Corrections of Errors'' sections below.

II. Summary of Errors

A. Standardized API for Patient and Population Services

As discussed in the preamble of the interim final rule, page 70077, second column, top of page, we stated that we added a new paragraph at § 170.315(g)(10)(v)(A)(*1*)(*iii*). However, in the amendatory instruction for the regulation text, we inadvertently added the wrong citation. In amendatory instruction 11.b., on page 70083, the words ''Adding paragraph (g)(10)(iv)(A)(*1*)(iii)'' should have read ''Adding paragraph (g)(10)(v)(A)(*1*)(*iii*).'' We are correcting the error by including the correct citation in this document.

B. Real World Testing

In the interim final rule, on page 70076, second column, top half of the page, we corrected the real world testing regulation text in § 170.405(b)(3) by removing the words ''for C–CDA'' from the heading of the paragraph (85 FR 70076). In § 170.405, we also extended the compliance dates for updating certain criteria until December 31, 2022 (85 FR 70072). However, in amendatory instruction 16.a., on page 70084, we inadvertently only included the instruction for ''(b)(3) introductory text,''. Because the revisions are being made to both the heading of § 170.405(b)(3) and the compliance date in § 170.405(b)(3)(ii), we are correcting the error in the amendatory instruction by adding ''(b)(3)(ii),'' after the phrase ''(b)(3) introductory text,''.

III. Waiver of Proposed Rulemaking, Comment Period, and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rulemaking in the **Federal Register** before the provisions of a rule take effect. In addition, section 553(d) of the APA mandates a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date requirements. Section 553(b)(B) of the APA authorizes an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, section 553(d)(3) of the APA allows the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe this correcting document does not constitute a rule that would be subject to the APA notice and comment or delayed effective date requirements. This document corrects typographical errors in regulation text of the interim final rule, but does not make substantive changes to the policies that were adopted in the interim final rule. As a result, this correcting document is intended to ensure that the information in the interim final rule accurately reflects the policies adopted in that final rule.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such procedures and requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the interim final rule or delaying the effective date would be contrary to the public interest because they are obvious typographical errors that are being corrected. Furthermore, such procedures would be unnecessary, as we are not making substantive changes to our methodologies or policies, but rather, we are simply implementing correctly the policies that we previously proposed, requested comment on, and subsequently finalized. This correcting document is intended solely to ensure that the ONC Cures Act Final Rule and the interim final rule accurately reflect these policies. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements.

IV. Corrections of Errors

In FR Doc 2020–24376 appearing on page 70064 in the **Federal Register** of Wednesday, November 4, 2020, for the reasons stated above, the Office of the Secretary corrects the following:

§ 170.315 [Corrected]

■ 1. On page 70083, in the first column, the text of amendatory instruction 11 is corrected to read as follows:

■ 11. Amend § 170.315 by:

■ a. Revising paragraphs (b)(1)(iii)(A)(*2*), (b)(2)(i), (b)(2)(iii)(D) introductory text, (b)(2)(iv), (b)(3)(ii)(B)(*2*), (b)(7)(ii), (b)(8)(i)(B), (b)(9)(ii), (c)(3), (d)(13)(ii), (e)(1)(i)(A)(*2*), (f)(5)(iii)(B)(*1*) and (*2*), (g)(6)(i)(B), (g)(9)(i)(A)(*2*), (g)(10)(v)(A)(*1*)(*ii*), and (g)(10)(v)(A)(*2*)(*ii*); and

■ b. Adding paragraph (g)(10)(v)(A)(*1*)(*iii*).

The revisions and addition read as follows:

§ 170.405 [Corrected]

■ 2. On page 70084, in the second column, the text of amendatory instruction 16 is corrected to read as follows:

■ 16. Amend § 170.405 by:

■ a. Revising paragraphs (b)(1) introductory text, (b)(2)(ii) introductory text, (b)(3) introductory text, (b)(3)(ii), (b)(4)(ii), (b)(5)(ii), (b)(6)(ii), and (b)(7)(ii); and
■ b. Adding paragraph (b)(10).

The revisions and addition read as follows:

Wilma M. Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2020–26666 Filed 12–2–20; 4:15 pm]

BILLING CODE P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket No. 16–42, CS Docket No. 97–80; FCC 20–124; FRS 17231]

Expanding Consumers' Video Navigation Choices; Commercial Availability of Navigation Devices

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) eliminates outdated CableCARD support and reporting requirements and terminates related dockets.

DATES: Effective December 4, 2020.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Brendan Murray, *Brendan.Murray@fcc.gov,* of the Media Bureau, (202) 418–1573.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, FCC 20–124, adopted and released on September 4, 2020. The full text of this document is available for public inspection via ECFS (*http://www.fcc.gov/cgb/ecfs/*). To request these documents in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

In this Report and Order, we terminate a proceeding in which we sought comment on the adoption of new regulations for ''navigation devices''—devices that consumers use to access multichannel video programming and other services offered over multichannel video programming networks—and eliminate outdated CableCARD support and reporting requirements. Four years ago, the Commission published a notice of proposed rulemaking (NPRM) (81 FR 14033, March 16, 2016) that proposed a complex framework of regulations which would have required multichannel video programming distributors (MVPDs) to provide unbundled flows of programming information to third-party manufacturers, retailers, and software developers to enable them to create navigation devices in an attempt to assure a commercial market for navigation devices.[1] However, the record submitted in response to the NPRM raises serious and significant questions about whether the proposed rules would adequately protect multichannel video programming content. Moreover, the record fails to convince us that the proposal is necessary to accomplish its intended goal, and we conclude that the proposed regulations do not reflect the past four years of substantial marketplace changes in the delivery and consumption of video programming. Separately, we eliminate the CableCARD consumer support rules and the requirement that large cable operators report to the Commission about support and deployment of CableCARD modules because these regulations no longer serve a useful purpose and thus are no longer necessary.

Section 629 of the Communications Act of 1934, as amended (Act), directs the Commission to adopt regulations to assure the commercial availability of devices that consumers use to access multichannel video programming and other services offered over multichannel video programming networks. Section 629 further directs that the Commission shall not prescribe such regulations ''which would jeopardize the security of multichannel video programming and other services offered over multichannel video programming systems, or impede the legal rights of a provider of such services to prevent theft of service.'' Through a series of rulemakings, the Commission has adopted regulations intended to assure this commercial availability of devices. The bellwether requirement of these rulemakings, which led to the ''CableCARD'' standard, allows viewers to receive digital cable services by attaching their own equipment directly to the cable network. In 2005, to better monitor support for the then-nascent CableCARD technology, the Commission required the six largest cable operators to submit status reports to the Commission every 90 days that detail how these cable operators met ''their obligations to deploy and support CableCARD.'' (70 FR 36048, June 22, 2005).[2] In 2010, the Commission adopted regulations to further ensure cable operator support for retail CableCARD devices. (76 FR 40263, July 8, 2011).[3] In 2016, the Commission's NPRM proposed a new and complicated regulatory regime for navigation devices.[4]

We conclude that further Commission intervention in the navigation device marketplace is not necessary at this time. We have serious and unresolved concerns about the security of multichannel video programming and copyright licensing under the proposed rules. Moreover, we conclude that the record raises other substantial doubts about the wisdom and necessity of the complex regulations proposed in the NPRM. On the other hand, we find that the CableCARD consumer support rules no longer serve a useful purpose following the D.C. Circuit's 2013 decision in *Echostar Satellite L.L.C.* v. *FCC,* 704 F.3d 992 (D.C. Cir. 2013) (*Echostar*), and accordingly eliminate these rules. We also conclude that the 15-year-old CableCARD reporting requirement is no longer necessary.

Closing the 2016 Proceeding. In 2016, the Commission sought comment on the need for new rules to implement section 629. We conclude that we need not adopt any new rules at this time. Although the NPRM tentatively concluded that the Commission ''should adopt new regulations to further section 629,''[5] there is substantial evidence in the record challenging that tentative conclusion. The consequences of adopting the proposed regulations could be substantial and detrimental to consumers, copyright holders, and MVPDs, and thus we are reluctant to adopt these additional regulations to implement section 629, quite apart from the substantial doubts in the record as to whether they will help assure a commercial market for devices that

[1] *Expanding Consumers' Video Navigation Choices; Commercial Availability of Navigation Devices,* MB Docket No. 16–42 and CS Docket No. 97–80, Notice of Proposed Rulemaking & Memorandum Opinion and Order, 31 FCC Rcd 1544, 1558–82, paras. 25–78 (2016).

[2] *Implementation of Section 304 of the Telecommunications Act of 1996: Commercial Availability of Navigation Devices,* CS Docket No. 97–80, Second Report and Order, 20 FCC Rcd 6794, 6814–15, para. 39 (2005) (2005 Report and Order).

[3] *Implementation of Section 304 of the Telecommunications Act of 1996: Commercial Availability of Navigation Devices,* CS Docket No. 97–80 and PP Docket No. 00–67, Third Report and Order and Order on Reconsideration, 25 FCC Rcd 14657 (Third Plug and Play Report and Order), *recon. granted in part sua sponte,* Order on Reconsideration, 26 FCC Rcd 791 (2011).

[4] NPRM, 31 FCC Rcd at 1558–82, paras. 25–78.

[5] NPRM, 31 FCC Rcd at 1551, para. 13.

consumers can use to access multichannel video programming. In addition, the Commission last sought comment on these issues more than four years ago, and since then important changes have occurred in the video programming marketplace and delivery of those services via applications that run on subscriber-owned devices. Moreover, we note that since the record closed, the Government Accountability Office (GAO) concluded that the NPRM did not sufficiently analyze ''the extent to which internet-based providers affect consumer choice for video programming and what that change means for the importance of consumer choice for devices in the context of the Act.'' [6]

Section 629(b) of the Act prohibits the Commission from adopting regulations under section 629 that would jeopardize the security of multichannel video programming. Several programmers, MVPDs, and the U.S. Copyright Office express serious concerns that the proposed rules and the applications-based alternative would jeopardize the security of programming and licensing contracts between programmers and MVPDs. Although we recognize that some commenters claim that the proposed rules would not interfere with programmers' copyright interests, we have ongoing concerns about the security risks and licensing issues the proposed rules could introduce. For instance, many commenters argue that the proposed rules would undermine anti-piracy protections, reducing the incentives of parties to invest in new content. In addition, the Commission's proposal could force MVPDs, programmers, and copyright holders to violate the copyright licensing contract obligations to which they agreed, leading to costly and time-consuming litigation. Further, the record also raises licensing concerns with respect to the applications-based alternative, as commenters contend that this approach might lead to content to be distributed on terms to which programmers have not agreed and object to Commission involvement in the licensing process. Accordingly, in light of section 629(b) and the impact the proposed rules could have on the video programming marketplace generally, including the availability and quality of programming, we find that we should not adopt the proposed rules or the applications-based alternative.

We also note that it appears the policy goals that the Commission set forth in the NPRM are well underway to being met without additional Government regulation. The Commission stated in the 2016 NPRM that it wanted to ''let MVPD subscribers watch what they pay for wherever they want, however they want, and whenever they want, and pay less money to do so, making it as easy to buy an innovative means of accessing multichannel video programming (such as an app, smart TV, or set-top box) as it is to buy a cell phone or TV.'' [7] And according to NCTA—The internet & Television Association (NCTA), the nine largest MVPDs ''support apps that can be used to watch their content on hundreds of millions of consumer-owned devices, such as smart TVs; tablets; streaming sticks and devices such as Apple TV, Roku, Google Chromecast, and Amazon Fire; smartphones; game consoles; and personal computers.'' [8] Therefore, without Commission intervention, many MVPD subscribers can watch the services that they pay for wherever, however, and whenever they want on an array of innovative devices via many different applications. Given the current state of the video programming marketplace, we are concerned that adopting the proposals set forth in the NPRM would risk stifling innovation and deterring investment in this sector and, thus, could ultimately detract from Congress's overarching goal for a fully competitive market for navigation devices.

The 2017 GAO Report recommended that we ''analyze how the ongoing evolution in the video programming market affects competition in the related market for set-top boxes and devices, including how it affects the extent to which consumer choice for devices to access MVPD content remains a relevant aspect of the competitive environment'' [9] as part of our competition reports. We will continue to monitor the navigation marketplace to determine whether further regulation is necessary to assure a commercial market for navigation devices, consistent with the requirements of section 629.

CableCARD Support and Reporting Requirements. We are eliminating the CableCARD consumer support rules. We conclude that these rules no longer serve a useful purpose following the D.C. Circuit's 2013 decision in *Echostar.* We acknowledge that the NPRM tentatively concluded that the CableCARD support rules continue to serve a useful purpose and should be retained. Nevertheless, after further consideration, we are unpersuaded by assertions that these rules remain necessary to ensure that consumers have retail alternatives to leased set-top boxes and that cable operators continue to support retail CableCARD devices during their expected lifetime. The CableCARD support rules were intended to help ''assure the development of a retail market for devices that can navigate cable services'' by ''improv[ing] consumers' experience with retail navigation devices . . . and CableCARDs.'' (76 FR 40263, July 8, 2011).[10] However, during the ten years in which these rules have been in effect, consumer demand for retail CableCARD devices never developed as anticipated. Indeed, in the four years since the NPRM in this proceeding was issued, consumer demand for retail CableCARD devices has steadily declined. We agree with NCTA that this decline in demand is partially attributable to the growing popularity of MVPD applications. MVPD applications are ubiquitous today, and consumers have fully embraced the use of such applications to access video programming. We note that the CableCARD support rules were intended to help advance the market for retail navigation devices ''[u]ntil a successor technology is actually available.'' (76 FR 40265, July 8, 2011).[11] MVPD applications are a new technology that is providing consumers an alternative to leased set-top boxes. Given that consumers have demonstrated a clear preference in recent years for applications over retail CableCARD devices, we expect that demand for retail CableCARD devices will only continue to fall. Accordingly, we conclude that retention of the CableCARD support rules is not necessary to ensure that consumers have retail alternatives to leased set-top boxes.

We also find that retention of the CableCARD support rules is unnecessary to ensure that cable operators continue to support retail CableCARD devices during their expected lifetime. As NCTA points out, cable operators are still required to provide separable security, and industry complies with this obligation through the use of CableCARDs, even after Echostar eliminated the mandate that the CableCARD standard be used by all MVPDs in implementing the separation of security requirement. NCTA also

[6] U.S. Gov't Accountability Office, GAO–17–785, FCC Should Conduct Additional Analysis to Evaluate Need for Set-Top Box Regulation, at 22 (2017) (GAO Report).

[7] NPRM, 31 FCC Rcd at 1551, para. 11.

[8] NCTA Comments, GN Docket No. 20–60, at 21–22.

[9] GAO Report at 22–23.

[10] Third Plug and Play Order, 25 FCC Rcd at 14658, para. 1.

[11] Third Plug and Play Order, 25 FCC Rcd at 14662, para. 8.

asserts that since there are tens of millions of CableCARDs currently deployed in cable operator-provided devices, ''[c]able operators have strong business incentives to ensure that CableCARDs continue to function properly.'' [12] We agree and further find that competitive market forces should incentivize cable operators to continue to support retail CableCARD devices. Given the continuing decline in cable subscribership and the vast array of streaming service options available to consumers today, we expect that cable operators will make every effort to retain subscribers by continuing to support retail CableCARD devices, even in the absence of the CableCARD support rules. We further note that one of the major concerns leading to the adoption of the CableCARD support rules was the cable industry's poor performance with regard to subscriber premise installations of CableCARDs in retail devices. Cable subscribers have come to expect self-installation options and we think it is exceedingly unlikely that cable operators will revert to requiring professional installations for retail CableCARD devices, particularly in light of issues raised by the current coronavirus pandemic.

Finally, we conclude that it is appropriate to eliminate the requirement that the largest cable operators report about CableCARD support and deployment on a quarterly basis. Much of the information required to be included in the reports is either repetitious or has little relevance today, and the reports filed in recent years reveal few problems with CableCARD deployment and the processes for resolving CableCARD implementation problems are generally unchanged from report to report. Thus, we see little practical utility in continuing to require the cable operators to report this information. We accordingly conclude that the quarterly status reports are no longer necessary to ensure that cable operators support retail CableCARD devices and we eliminate them.

Paperwork Reduction Act. This document does not contain any proposed, new, or modified information collection subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified ''information collection burden for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

[12] NCTA Comments at 173.

Final Regulatory Flexibility Act Analysis. The Report and Order interprets Section 629 of the Communications Act, 47 U.S.C. 549, and terminates the proceedings CS Docket No. 97–80 Commercial Availability of Navigation Devices and MB Docket No. 16–42 Expanding Consumers' Video Navigation Choices because of serious and significant questions about whether the proposed rules would protect programming outweigh the speculative benefits of proposed set-top box rules. The Report and Order also eliminates the CableCARD consumer support rules, concluding that these rules no longer serve a useful purpose following the D.C. Circuit's 2013 decision in *Echostar.* Finally, the Report and Order eliminates the requirement that the largest cable operators submit status reports to the Commission every 90 days that detail show the cable operators meet ''their obligations to deploy and support CableCARDs.'' (70 FR 36048, June 22, 2005).[13]

Several commenters raised concerns that the proposed rules would be disproportionately and significantly burdensome on small MVPDs and asked the Commission to exempt small MVPDs from the final regulations. The Report and Order concludes, however, that the proposed rules should not be adopted and that the proceeding should be terminated. Accordingly, there is no need to address these comments.

Pursuant to the Small Business Jobs Act of 2010, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration, and to provide a detailed statement of any change made to the proposed rules as a result of those comments. The Chief Counsel filed comments expressing concern that ''that the FCC's proposed rules will be disproportionately and significantly burdensome for small [MVPDs]'' and urging the FCC to ''exempt small MVPDs when it finalizes its new rules.'' [14] The Report and Order concludes that the proposed rules should not be adopted and that the proceeding should be terminated. Accordingly, there is no need to respond to the comments of the Chief Counsel.

The rule changes adopted herein will directly affect small cable television operators by eliminating the regulatory CableCARD support requirements.

[13] 2005 Report and Order, 20 FCC Rcd at 6814–15, para. 39.

[14] Letter from Darryl L. DePriest, Chief Counsel for Advocacy, U.S. Small Business Administration, Office of Advocacy, to Marlene H. Dortch, Secretary, FCC, MB Docket No. 16–42, at 1 (June 6. 2016).

Ordering Clauses. For the reasons stated above, *it is ordered* that, pursuant to the authority found in sections 4(i), 4(j), 303(r), and 629 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 303(r), and 549 that this Report and Order *is adopted. It is further ordered* that the Commission's rules *are amended* as set forth below. *It is further ordered* should no petitions for reconsideration or petitions for judicial review be timely filed, CS Docket No. 97–80 and MB Docket No. 16–42 *shall be terminated* and the dockets *closed. It is further ordered* that the Commission *shall send* a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 76

Administrative practice and procedure, Cable television, Communications, Equal employment opportunity, Internet, Political candidates, Reporting and recordkeeping requirements, Telecommunications.

Federal Communications Commission.

Marlene Dortch,

Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 76 as follows:

PART 76—MULTICHANNEL VIDEO AND CABLE TELEVISION SERVICE

■ 1. The authority citation for part 76 continues to read as follows:

Authority: 47 U.S.C. 151, 152, 153, 154, 301, 302, 302a, 303, 303a, 307, 308, 309, 312, 315, 317, 325, 338, 339, 340, 341, 503, 521, 522, 531, 532, 534, 535, 536, 537, 543, 544, 544a, 545, 548, 549, 552, 554, 556, 558, 560, 561, 571, 572, 573.

■ 2. Revise § 76.1205 to read as follows:

§ 76.1205 Availability of interface information.

Technical information concerning interface parameters that are needed to permit navigation devices to operate with multichannel video programming systems shall be provided by the system operator upon request in a timely manner.

[FR Doc. 2020–25143 Filed 12–3–20; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 85, No. 234
Friday, December 4, 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 JUSTICE

Executive Office for Immigration Review

8 CFR Parts 1001, 1003, 1208, 1214, 1240, 1245, 1246, 1292

[EOIR Docket No. 18–0203; Dir. Order No. 04–2021]

RIN 1125–AA81

Executive Office for Immigration Review Electronic Case Access and Filing

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Executive Office for Immigration Review (''EOIR'') is proposing to implement electronic filing and records applications for all cases before the immigration courts and the Board of Immigration Appeals (''BIA''). The proposed rule would update the relevant regulations necessary to implement these electronic filing and records applications, including requiring certain users to file documents electronically and changes to service of process. EOIR further proposes clarifications to the regulations regarding law student filing and accompaniment procedures.

DATES: Electronic comments must be submitted and written comments must be postmarked or otherwise indicate a shipping date on or before January 4, 2021. The electronic Federal Docket Management System at *https://www.regulations.gov* will accept electronic comments until 11:59 p.m. Eastern Time on that date.

ADDRESSES: If you wish to provide comment regarding this rulemaking, you must submit comments, identified by the agency name and reference RIN 1125–AA81 or EOIR Docket No. 18–0203, by one of the two methods below.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the website instructions for submitting comments.
- *Mail:* Paper comments that duplicate an electronic submission are unnecessary. If you wish to submit a paper comment in lieu of electronic submission, please direct the mail/shipment to: Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 1800, Falls Church, VA 22041. To ensure proper handling, please reference the agency name and RIN 1125–AA81 or EOIR Docket No. 18–0203 on your correspondence. Mailed items must be postmarked or otherwise indicate a shipping date on or before the submission deadline.

FOR FURTHER INFORMATION CONTACT: Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 1800, Falls Church, VA 22041, telephone (703) 305–0289 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this proposed rule via the one of the methods and by the deadline stated above. All comments must be submitted in English, or accompanied by an English translation. The Department of Justice (the ''Department'') also invites comments that relate to the economic, environmental, or federalism effects that might result from this proposed rule. Comments that will provide the most assistance to the Department in developing these procedures will reference a specific portion of the proposed rule; explain the reason for any recommended change; and include data, information, or authority that support such recommended change.

Please note that all comments received are considered part of the public record and made available for public inspection at *https://www.regulations.gov.* Such information includes personally identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personally identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONALLY IDENTIFYING INFORMATION'' 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 posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You also must prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *https://www.regulations.gov.*

Personally identifying information located as set forth above will be placed in the agency's public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. The Department may withhold from public viewing information provided in comments that they determine may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.* To inspect the agency's public docket file in person, you must make an appointment with the agency. Please see the **FOR FURTHER INFORMATION CONTACT** paragraph above for agency contact information.

The Department may withhold from public viewing information provided in comments that they determine may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

II. Background

A. Introduction

Since July 2018, EOIR has been piloting a voluntary program to test electronic filing and records applications for certain cases filed with the immigration courts and the BIA. *See* EOIR Electronic Filing Pilot Program, 83 FR 29575 (June 25, 2018). Following this successful pilot at five immigration courts, EOIR is now proposing to permanently implement these electronic

filing and records applications at the immigration courts and the BIA. This proposed rule would amend the regulatory sections necessary to implement the electronic filing and records applications.

B. History

In 1998, Congress passed the Government Paperwork Elimination Act (''GPEA''), which requires federal agencies to provide the public with the ability to conduct business electronically, when practicable, with the federal government. *See* Public Law 105–277, § 1701–10, Oct. 21, 1998, 112 Stat. 2681, 2681–749 to –751. Similarly, in 2002, Congress passed the E-Government Act of 2002, which promotes electronic government services and requires agencies to use internet-based technology to increase the public's access to government information and services. *See* Public Law 107–347, Dec. 17, 2002, 116 Stat. 2899.

As a result, EOIR began pursuing a long-term agency plan to create electronic case access and filing applications for the immigration courts and BIA. *See* Executive Office for Immigration Review Attorney/Representative Registry, 68 FR 75160, 75161 (Dec. 30, 2003) (''The Department is . . . designing an electronic case access and filing system, to comply with the [GPEA], to achieve the Department's vision for improved immigration adjudication processing, and to meet the public expectations for electronic government.''). Under the GPEA, where practicable, executive branch agencies are to provide for electronic submissions in lieu of paper submissions and for the use of electronic signatures. 44 U.S.C. 3504(a)(1)(B)(vi).

On April 1, 2013, EOIR completed the first portion of its public-facing electronic applications by establishing eRegistry, a mandatory electronic registry for all attorneys and fully accredited representatives who practice before the immigration courts and the BIA.[1] *See* Registry for Attorneys and Representatives, 78 FR 19400 (Apr. 1, 2013). At the same time, EOIR began allowing attorneys and accredited representatives[2] to electronically file the Notice of Entry of Appearance as Attorney or Representative (Form EOIR–27 and Form EOIR–28, for the BIA and immigration courts, respectively).

On May 4, 2015, EOIR launched ''eInfo,'' a web-based application that allows registered attorneys and accredited representatives to view their clients' case information. *See* EOIR, *The Executive Office for Immigration Review Announces I*[3] (May 4, 2015), *https://www.justice.gov/eoir/pr/executive-office-immigration-review-announces-i.* Attorneys and accredited representatives can log into the eInfo application to view a list of cases for which they have an active Notice of Entry of Appearance (Form EOIR–27 or Form EOIR–28) and view case-related information.

Since June 2017, EOIR has been undertaking additional and more expansive initiatives to reduce its longstanding backlog of cases and working to ensure the more efficient handling of matters before the immigration court system. As part of that plan, in July 2018, EOIR launched a pilot program to allow attorneys and accredited representatives to electronically file case-related documents with the immigration courts and the BIA, and for EOIR to process cases using an electronic record of proceeding (''eROP''). *See* 83 FR at 29575. The pilot launched in five immigration courts between July and December 2018: San Diego, California in July; Atlanta, Georgia and Denver, Colorado in August; Baltimore, Maryland in September; and York, Pennsylvania in December.[3] The BIA has participated in the pilot for operational planning purposes but is not yet accepting electronic filings. As of September 2020, more than 15,000 private attorneys had volunteered to participate, representatives and immigration court staff had electronically uploaded more than 500,000 documents, and court staff had created more than 80,000 eROPs.

EOIR is continuing to expand the rollout of this system, which will eventually expand to all immigration courts and the BIA. The EOIR Courts and Appeals System (''ECAS'') is now available in several immigration courts and adjudication centers. Information regarding the full implementation schedule will be posted on EOIR's website. EOIR, *EOIR Courts & Appeals System (ECAS)—Online Filing,* (Oct. 5, 2020) *https://www.justice.gov/eoir/ECAS.*

III. Proposed Rule

This proposed rule would provide for EOIR's implementation of the electronic filing and records applications that are currently in use in several immigration courts and the BIA.

Following the launch of the electronic filing and records applications in each immigration court, all cases in which the Department of Homeland Security (''DHS'') files a charging document in that court after the launch date are processed electronically, meaning that EOIR will maintain an eROP as the official record of proceeding for that case. Regardless of whether all parties are participating in the electronic filing and records applications, EOIR will maintain an eROP for such cases. If a document is filed on paper, EOIR will scan the document into the eROP and maintain the eROP as the official record of proceeding. In addition, attorneys and accredited representatives may submit bond redetermination requests electronically with that court, which EOIR will then process electronically. For more information about the privacy risks associated with the eROP, and the measures EOIR has taken to protect this information, please see EOIR, *Privacy Impact Assessment for the eWorld Adjudication System,* 19–24 (Dec. 13, 2018), *https://www.justice.gov/opcl/page/file/1120991/download.*

Appeals of immigration judge decisions filed with the BIA will similarly be processed electronically following the launch of the electronic filing and records applications system at the BIA. Appeals of immigration judge decisions, appeals from DHS officer decisions,[4] and motions to reopen or reconsider filed with the BIA will follow existing legal process, but will be filed and processed electronically. All cases initiated at an immigration court or the BIA before the launch of the electronic filing and records

[1] The EOIR regulations differentiate between ''partially accredited representatives'' who are only authorized to represent persons in matters pending before the Department of Homeland Security (''DHS''), and ''fully accredited representatives'' who are authorized to represent persons in matters pending before EOIR as well as matters pending before DHS. *See* 8 CFR 1292.1(a)(4). Inasmuch as this rule pertains only to practice before EOIR, the only accredited representatives who would be affected by this rule are fully accredited representatives. Accordingly, the references in this rule to ''accredited representatives'' refer only to fully accredited representatives in the context of their practice before EOIR.

[2] EOIR's Office of Policy reviews recognized organizations' applications for non-attorneys to become fully accredited representatives who, upon approval, can represent aliens in immigration court proceedings and before DHS. For more information, please see EOIR, *Recognition & Accreditation (R&A) Program* (June 8, 2020), *https://www.justice.gov/eoir/recognition-and-accreditation-program.*

[3] Charlotte was originally scheduled as a pilot location in September 2018, but the pilot there was cancelled due to Hurricane Florence. Similarly, York was moved from July 2018 to December 2018 to accommodate additional internal development to ensure ECAS functionality for detained courts.

[4] For appeals of DHS officer decisions that are subject to review by the BIA, the process for DHS would not change under this rule as DHS currently submits all of those materials to the BIA for adjudication, and it will continue to do so. *See* 8 CFR 1003.5(b).

applications in that location will continue to be processed in paper by EOIR, and will continue to require the parties to paper file documents in those cases. Similarly, if a case begins in an immigration court with an eROP, and then changes venue to an immigration court that has not yet implemented the electronic filing and records applications, that case will be converted to a paper record and processed in paper at the new court. In the future, EOIR may explore converting existing paper records into eROPs following the launch of the electronic filing and records applications at the immigration court with administrative control over the paper record of proceeding (''ROP''); such conversion would also depend on the cost and technological feasibility.

Once this proposed rule is adopted in final form, electronic filing will become mandatory for all attorneys and accredited representatives, with limited exceptions as discussed further below. This includes mandatory electronic filing of charging documents initiated by DHS, 8 CFR 1003.13 (defining charging documents), and mandatory electronic filing of other documents.[5] However, until this proposed rule is adopted in final form, participation in the pilot program at any court where EOIR has launched the electronic filing capabilities or the BIA will remain voluntary under the terms of the existing pilot program. Similarly, immigration courts and the BIA will continue to follow existing procedures for sending and receiving case-related materials in those cases where the attorney or accredited representative has not agreed to participate in the pilot program. In order to complete this full nationwide implementation, EOIR is proposing to make the following changes to its regulations.

A. Filing

1. Who May File Electronically

This rulemaking proposes that electronic filing will become mandatory for DHS[6] and attorneys and accredited representatives who represent respondents, applicants, or petitioners before EOIR. By mandating electronic filing for attorneys and accredited representatives, EOIR will be able to maintain a complete electronic process for many cases from beginning to end. EOIR anticipates that this will create significant efficiencies for the parties and EOIR. For example, registered parties will be able to file documents electronically at any time of day from any location with internet access, removing concerns related to the restrictions business hours create to meet filing deadlines (*i.e.,* representatives can file after court hours rather than appearing in person at the court or a mail delivery service office during certain hours). Once the electronic filings are accepted, the parties will be able to view all of the documents filed in their case without having to appear at an immigration court to view the paper record. Parties will be required to make all original paper copies of any electronically filed documents available for review upon request of the immigration court, BIA, or the opposing party. Similarly, EOIR will be able to quickly process filings and maintain case records through an electronic system.

To provide for possible unanticipated issues arising from mandating electronic filing, this rule proposes to allow for an extended filing deadline when the electronic filing system is unavailable due to an unplanned system outage and to provide immigration judges with the authority to accept paper filings in open court in limited circumstances, including for rebuttal or impeachment purposes; for good cause shown, provided that the filing is otherwise admissible and the immigration judge finds that any applicable filing deadline should be excused; or, when the opposing party does not object to the paper filing.

EOIR also intends to make electronic filing through ECAS available on a voluntary basis to *pro se* respondents, applicants, or petitioners and to reputable individuals and accredited officials, as defined in 8 CFR 1292.1(a)(3) and (a)(5), respectively, because all of the same efficiencies listed above may also flow to those individuals if they choose to use ECAS. Both reputable individuals and accredited officials may act as representatives in immigration proceedings before EOIR and are subject to the same requirements as other representatives, such as the need to file a Form EOIR–28 when making an appearance or receiving service of process in a particular case. *See, e.g.,* 8 CFR 1292.4(a), 1292.5(a). EOIR also recognizes that both types of representatives appear sparingly in proceedings before EOIR, and both reputable individuals and accredited officials, as defined in the regulations, may not have the same sort of familiarity with EOIR's procedures and requirements as other types of representatives. *Cf.* 8 CFR 1292.1(a)(3)(iv) (providing that, in order to qualify as a reputable individual, a person may not be one who ''regularly engages in immigration and naturalization practice or preparation''). Although *pro se* respondents, applicants, or petitioners and reputable individuals and accredited officials are not currently able to participate in the electronic filing program, this capability will eventually be available for those who opt to use it, and EOIR will adapt its current registration system as appropriate to allow *pro se* respondents, applicants, or petitioners and reputable individuals and accredited officials to register in order to be able to utilize ECAS. The rulemaking proposes changes to allow for this future ECAS utilization capability by *pro se* respondents, applicants, or petitioners and reputable individuals and accredited officials.[7]

EOIR seeks comment on these considerations, including how to best register such users for electronic filing, whether the same two-factor authentication process used for attorneys and accredited representatives would similarly work for these users, whether there are other more effective methods for identity-proofing online filers who do not have the same

[5] Non-documentary filings (*e.g.,* proposed audio or video exhibits) are not contemplated under existing regulations. *See, e.g.,* 8 CFR 1003.31, 1003.32, 1003.33 (all referring to ''documents''). Nevertheless, consistent with an immigration judge's authority to make determinations regarding removability and applications, 8 CFR 1240.1(a)(1)(i)–(ii), and an immigration judge's authority to take action consistent with the law to decide cases before them, 8 CFR 1003.10(b), such filings may be considered subject to an immigration judge's discretion. The proposed rule does not alter that practice. Consequently, because security protocols may prevent the direct uploading of audio or video files into ECAS as filings, parties wishing to submit non-documentary filings in cases with an eROP should continue to file them in a physical format (*e.g.,* a CD or DVD) directly with the relevant immigration court. Such non-documentary filings, subject to the immigration judge's discretion, may then be incorporated into the eROP as appropriate.

[6] DHS includes all relevant DHS components. *See* 8 CFR 1001.1(w). DHS will determine which of its employees are responsible for filing documents in ECAS in individual cases.

[7] Although opting in for electronic filing through ECAS is voluntary for *pro se* respondents, applicants, or petitioners and for reputable individuals and accredited officials, such individuals who choose to opt in will do so for the life of the case and may not opt out without leave from an immigration judge or, for cases pending with the BIA, from the BIA. This qualification sets clear expectations for the individual and reduces the likelihood of confusion among the individual, the opposing party, and the immigration court staff regarding documents filed multiple times through different methods, of the possible loss of documents filed in a manner inconsistent with how the official record of proceeding is being kept, and of the improper effectuation of service on the opposing party.

financial or U.S. ''footprint'' that can be used for remote verification of the person's identity, and how to combat any potential fraud concerns related to expanding electronic filing capabilities to parties other than attorneys and accredited representatives. For more information on the current registration process for eRegistry, please see EOIR, *Frequently Asked Questions: Attorneys and Accredited Representatives* (Oct. 1, 2020), *https://www.justice.gov/eoir/ecas/attorney-and-ar-FAQs.*

EOIR also proposes to change how law students and law graduates, as defined in 8 CFR 1292.1(a)(2), file documents and appear before EOIR. The Immigration and Nationality Act (''INA'') provides that aliens appearing before an immigration judge ''shall have the privilege of being represented, at no expense to the Government, by counsel of the alien's choosing who is authorized to practice in such proceedings.'' INA 240(b)(4)(A), 8 U.S.C. 1229a(b)(4)(A); *see also* INA 292, 8 U.S.C. 1362. The Attorney General possesses a general authority to ''establish such regulations . . . as the Attorney General determines to be necessary for carrying out'' his authorities under the INA. INA 103(g)(2), 8 U.S.C. 1103(g)(2). Pursuant to this authority, this rule proposes to clarify the circumstances under which law students and law graduates are authorized to practice in immigration proceedings.

There is no statutory entitlement for law students and law graduates to participate as representatives in immigration proceedings. Rather, the Department has authorized law student representation subject to attorney supervision as a matter of regulatory grace since at least 1975. Representation and Appearance Before Immigration and Naturalization Service and Board of Immigration Appeals, 40 FR 23271 (May 29, 1975). Over time, the Department had modified the regulations governing law student and law graduate practice on multiple occasions. *See, e.g.,* Representation and Appearance, 55 FR 49250 (Nov. 27, 1990) (expanding participation of law students in clinical programs at accredited law schools from only third-year law students to first and second-year students); Executive Office for Immigration Review; Representation and Appearances: Law Students and Law Graduates, 62 FR 23634 (May 1, 1997) (clarifying that law students and law graduates could participate through programs outside of law school clinics and that the prohibition on direct or indirect remuneration for law students and law graduates applies only to remuneration from respondents). The most recent change occurred in 2008, when the Department clarified ''that law students and law graduates must be students and graduates of accredited law schools in the United States'' in order to practice before EOIR. Professional Conduct for Practitioners—Rules and Procedures, and Representation and Appearances, 73 FR 76914, 76916 (Dec. 18, 2008).

As the Department moves toward electronic filing capability for all cases in immigration proceedings, it finds that additional clarifications are warranted to ensure that appropriate attorney supervision over law students and law graduates is maintained and that respondents are not prejudiced by the intrinsically transient nature of such representation. *Cf.* 78 FR at 19400, 19404 (declining to require law students to register with EOIR due to, among other things, ''the transient nature of law students' participation in clinical programs and the limited circumstances under which students can represent individuals before EOIR . . . the absence of any mechanism to inform EOIR when a student leaves a program . . . [and the lack of a] regulatory provision permitting a law student to appear before EOIR if not enrolled in a 'legal aid program or clinic,' [making] it . . . problematic for those students to remain registered after leaving a clinical program'').

The proposed rule clarifies that all filings by law students must be made through an attorney or accredited representative who is registered with EOIR pursuant to 8 CFR 1292.1(f). As currently drafted, the regulations require ''direct supervision'' of law students, 8 CFR 1292.1(a)(2)(ii), but do not provide a clear definition of that term. Further, this rulemaking proposes that law graduates, currently required to have ''supervision'' under the regulations, 8 CFR 1292.1(a)(2)(iii), would also need to file through an attorney or accredited representative registered with EOIR. Law students and law graduates often provide representation through clinics or other short-term programs, which limits the length of their representation and can create confusion that affects the respondent when such short-term representation results in a change of counsel. With electronic filing, it is critical that the court can reach the supervising attorney and that the attorney is familiar with the proceedings, similar to the requirement that the clinic's address be provided for court communications rather than a student's personal address.

By requiring filings be completed through a supervising attorney or accredited representative, EOIR will be able to ensure that there is a single representative responsible for receiving electronic service from EOIR for the duration of the proceeding. For example, EOIR wants to prevent a scenario where electronic service of an important, time-sensitive document is sent to a law student who, since the last hearing, has left a law school clinic and is not expecting any EOIR-related emails. In practice, this will also increase the use of electronic filing because, under this proposed rule, the supervising attorney or accredited representative will be required to file documents electronically with EOIR. To protect the integrity of the filings, and proceedings as a whole, only registered attorneys and fully accredited representatives will be able to file electronically. The supervising attorney or accredited representative must be the filer to ensure that an attorney or representative authorized to practice before EOIR performs their supervisory role and takes ultimate responsibility for official filings. This change is also consistent with existing requirements in many states regarding law student practice. *See, e.g.,* Ga. Sup. Ct. R. 95(4) (''An attorney who supervises a registered law student shall . . . review, approve and personally sign any document prepared by a student that is filed in any court or tribunal, and review and approve any document prepared by a student that would have binding legal effect on a person or entity receiving services in relation to activities of the student registered pursuant to this Rule''); Wash. Ad. and Prac. R. 9(f)(4) (a supervising lawyer of a licensed legal intern ''must review and sign all correspondence providing legal advice to clients and all pleadings, motions, briefs, and other documents prepared by the Licensed Legal Intern and ensure that they comply with the requirements of this proposed rule, and must sign the document if it is prepared for presentation to a court'').

In addition, this rulemaking proposes that a law student or law graduate is authorized to practice only if a supervising attorney or accredited representative physically accompanies the law student or law graduate during all immigration court appearances.[8] The supervising attorney or accredited representative must enter an appearance in the case and be physically present

[8] Nothing in the proposed rule precludes a law student or law graduate from appearing telephonically provided the immigration judge has approved such appearance. In such cases, the supervising attorney or accredited representative would be expected to be present with the law student or law graduate by telephone.

and prepared to proceed in case of the inability of the law student or law graduate to do so. The current regulation requires the supervisor to accompany the law student or graduate at the request of the immigration judge or BIA but does not require the supervisor to enter an appearance in the case. As with the proposed filing change for law students, this change is similarly intended to ensure that every case has a representative who is aware of the case and proceedings and is ultimately responsible for proper representation in that case.

Moreover, this change is consistent with many state bar rules allowing the practice of law by a law student in limited situations, but with the presence of a supervising attorney for adjudicatory proceedings. *See, e.g.,* N.Y. R. Ct. 805.5(e) (''The supervising attorney shall assume personal professional responsibility for any work undertaken by a law intern and shall supervise the preparation of the intern's work. Immediate supervision of a law intern shall mean that *the supervising attorney shall be personally present throughout the proceedings.*'' (emphasis added)); Tenn. R. Sup. Ct. 7, sec. 10.03(h)(2) (''It is the responsibility of the supervising attorney to ensure that the student is properly supervised and instructed . . . *and be present for administrative or adjudicatory proceedings*'' (emphasis added)). Additionally, by requiring the supervising attorney or representative to physically [9] accompany the law student or law graduate, this proposed rule intends to avoid unnecessary delays if the law student or graduate is unable to proceed with representation. The supervising attorney or representative would also need to enter an appearance in order to be able to electronically file documents as required by this proposed rule.

This rulemaking also proposes to limit who may accompany the law student or law graduate to attorneys and accredited representatives and to remove the term ''supervising faculty member.'' This proposed change is not intended to prevent faculty members from supervising law students, and most law school clinical supervising faculty members are already attorneys. Rather, this change would simply require supervising faculty members to be attorneys or accredited representatives authorized to practice before EOIR, in order to support the goal that a licensed attorney or accredited representative be ultimately responsible for filings and appearances before EOIR and to avoid potentially problematic circumstances in which a law student or law graduate is being supervised by a non-attorney or non-accredited representative, possibly in contravention of relevant state bar rules.

2. Registration Process

In order to file electronically with EOIR, an attorney or accredited representative must be registered with EOIR. Under existing EOIR regulations, all attorneys or accredited representatives are already required to enroll in eRegistry as a condition of practice before the immigration judges or the BIA. *See* 8 CFR 1292.1(f). Accordingly, no further registration would be required under this proposed rule for attorneys or accredited representatives.

However, in the event that EOIR decides to expand electronic filing in the future to persons other than attorneys or accredited representatives, EOIR anticipates that those persons who are not currently enrolled in eRegistry would be required to complete a one-time registration through EOIR's eRegistry application, consistent with current practice.

The eRegistry system requires the user to complete an online application and, once that application is complete, present identification in person at an immigration court or the BIA.[10] Once the user is registered through eRegistry, the user will receive an EOIR ID that will allow the user to log in to the electronic filing applications and view cases and file documents.[11]

3. Cases Eligible for Electronic Filing

Registered users are only able to electronically file documents in a case if that case is eligible for electronic filing. ''Case eligible for electronic filing'' means any case that DHS seeks to bring before an immigration court after EOIR has formally established an electronic filing system for that court or any case before an immigration court or the BIA that has an eROP. All cases that are initiated at an immigration court or the BIA after that court or the BIA begins using the electronic filing and records applications will be processed with an eROP.

For example, if EOIR's electronic filing and records applications are implemented at the Los Angeles Immigration Court on November 20, 2020, all cases in which DHS files a charging document or the alien files a bond redetermination request at the Los Angeles Immigration Court on November 20, 2020 or later will be processed with an eROP and eligible for electronic filing. In contrast, all other pending proceedings at the Los Angeles Immigration Court initiated on November 19, 2020 or earlier will not be eligible for electronic filing, including motions to reopen filed in cases initiated before this date.

This rulemaking proposes to update 8 CFR 1001.1 to include this definition for ''case eligible for electronic filing.'' Users will be able to see whether a case has an eROP by logging into the electronic filing application and searching for the specific case. If the case allows documents to be uploaded through the electronic filing application, then the case has an eROP. If there is no upload option, then the case does not have an eROP, and all documents must be paper filed with the proper immigration court or the BIA, as appropriate.

4. Electronic Filing Application Availability

The proposed regulation would provide guidance for how a party subject to electronic filing requirements should proceed if EOIR's electronic filing system is unavailable. If EOIR's electronic filing system is unavailable due to an unplanned system outage on the last day for filing in a specific case, EOIR would evaluate the overall impact and make appropriate filing deadline adjustments (*e.g.,* extensions to the first day that the electronic filing system becomes accessible that is not a Saturday, Sunday, or legal holiday for those cases impacted). EOIR would determine whether the electronic filing system is unavailable due to a system outage sufficient to trigger the extended filing deadline, and EOIR would communicate such outages to external users through email, EOIR's website, or other methods of communication, as available. Of course, parties maintain the ability to request an extension from the immigration court or BIA or to submit a motion to accept an untimely filing. *See* Office of the Chief Immigration Judge, Immigration Court Practice Manual 37, 39–40 (Nov. 16, 2020), *https://www.justice.gov/eoir/page/file/1258536/download* (last visited Nov. 19, 2020) (''Immigration

[9] If the law student or law graduate were appearing by telephone or video teleconferencing, the supervising attorney or representative would still need to be physically present with the law student or law graduate but would not need to be physically present in the immigration court.

[10] For more information on the eRegistry process, please see EOIR, *EOIR Courts & Appeals System (ECAS)—Online Filing* (Oct. 5, 2020), *https://www.justice.gov/eoir/ECAS.*

[11] For information regarding the mechanics of the actual electronic filing process, please see EOIR, *ECAS User Manual, https://www.justice.gov/eoir/page/file/1300086/download.*

Court Practice Manual''); Board of Immigration Appeals, Board of Immigration Appeals Practice Manual, 34, 66 (Oct. 5, 2020), *https://www.justice.gov/eoir/page/file/1324276/download* (last visited Nov. 19, 2020) (''BIA Practice Manual''). Both the immigration court and the BIA have the discretion to accept untimely filings. *See* Immigration Court Practice Manual, at 39–40; BIA Practice Manual, at 66. Additionally, in the event that EOIR's electronic filing system is unavailable, parties are permitted to file paper motions or requests for extensions.

This unplanned unavailability policy tracks the federal courts' policy for their electronic filing system. *See* Fed. R. Civ. P. 6(a)(3)(A); Fed. R. App. P. 26(a)(3)(A). It also follows the electronic filing requirements for many state judicial systems as well. *See, e.g.,* Tenn. R. Sup. Ct. 46, sec. 5.02 (''In the event the e-filing system is offline for technical reasons for a significant portion of a particular day, the clerk, in his or her discretion, is authorized to issue a written declaration that the e-filing system is unavailable for filing on that day, in which event all filings due on that day from Registered Users shall be deemed to be timely if filed the following day.'').

On the other hand, if EOIR's electronic filing system is unavailable due to a planned, previously announced [12] system outage on the last day for filing in a specific case, this proposed rule would provide that the user must plan accordingly to electronically file the documents during system availability or be prepared to file the documents on paper with the proper immigration court or the BIA in order to meet any applicable filing deadlines. EOIR would communicate these planned outages to external users through email, EOIR's website, or other methods of communication, as available.

This proposed rule would not change the immigration judges' or BIA's authority to determine how to treat an untimely filing or prevent parties from making a motion to accept the untimely filing. *See* Immigration Court Practice Manual, at 39–40; BIA Practice Manual, at 33–40.

5. Filing Classified Information

EOIR's electronic filing and records applications are not rated for classified information. Users should not file classified information through EOIR's electronic filing application, and the application does not change the users' or the agency's responsibilities related to classified information. Users would need to file any classified information by paper and follow existing procedures for the filing of classified information. *See* EOIR, Operating Policies and Procedures Memorandum 09–01, *Classified Information in Immigration Court Proceedings* (Feb. 5, 2009), *https://www.justice.gov/sites/default/files/eoir/legacy/2009/02/11/09-01.pdf.* EOIR immigration court staff will maintain a paper record for any filing that contains classified information.

6. Receipt and Rejection of Filings

EOIR also proposes to move and update the ''filing'' definition currently located in 8 CFR 1003.13 to the general definition section in 8 CFR 1001.1 so that it will apply to both the immigration courts and the BIA. That proposed definition further explains when both electronic and paper filings are deemed filed and makes clear that improper filings that are rejected are not deemed ''filed.'' [13] *See generally* Immigration Court Practice Manual, at 33–34, 38–40; BIA Practice Manual, at 31–33, 34. The bases for rejecting filings track those already applied by the BIA and the immigration courts as outlined in each's respective practice manual. *See* Immigration Court Practice Manual, at 33–34, 38–40; BIA Practice Manual, at 31–334.

B. Service

This rulemaking also proposes to change how service of process is accomplished in cases before the immigration courts and the BIA. Currently, the parties must simultaneously serve on the opposing party a copy of all documents filed with the immigration courts and the BIA. *See, e.g.,* 8 CFR 1003.3(a)(1), (c)(1), 1003.23(b)(1)(ii), 1003.32(a). This service must be accomplished in person or by first-class mail. *See* 8 CFR 1003.32(a), *BIA Practice Manual,* at 36. Similarly, under the current regulations, the immigration courts and the BIA must serve copies of court documents, such as orders, notices, and decisions, in person or by mail. *See, e.g.,* 8 CFR 1003.1(f), 1003.37(a).

In this proposed rule, EOIR proposes to move the ''service'' definition currently located in 8 CFR 1003.13 to the general definition section in 8 CFR 1001.1 so that it will apply to both the immigration courts and the BIA. EOIR also proposes updates to various cross-references to service of process accordingly.

In order to provide a simpler and more efficient filing process, EOIR proposes to complete service electronically on behalf of the parties for all cases in which both parties are using electronic filing. When a party successfully uploads a document to EOIR's electronic filing application and the other party is also using electronic filing in that case, EOIR's application will send the parties an electronic notification that the eROP has been updated. This will simplify the filing process for electronic filers by only requiring them to file their documents with EOIR in eligible cases rather than needing to execute multiple mailings to complete service requirements.

On the other hand, if another party is not participating in electronic filing for that particular case, EOIR's electronic filing application will alert the user that the opposing party is not participating in electronic filing for that particular case and remind the filer of the responsibility to complete service of process on the opposing party. Consistent with existing practice, the filer must include a certificate of service with each filing as proof of completed service on the opposing party.

EOIR also proposes to update the ''service'' definition to allow parties and EOIR the option to complete service electronically. In situations where the parties need to complete service outside of the electronic filing application, the parties may complete service electronically,[14] or by personal or mail service, which are the current options for completing service. EOIR anticipates that this will provide significant efficiencies to the parties by eliminating the need to print and mail documents to each other.

EOIR further proposes to serve EOIR-generated documents, such as orders, decisions, and notices, by electronic notification to parties that are participating in electronic filing. This notification will constitute completed service and begin the appeal clock, if applicable. If a party is not participating

[12] Any system outage announced three or fewer business days prior to the start of the outage will be treated as an unplanned outage.

[13] Consistent with analogous state laws, the proposed definition also recognizes a discretionary safety valve to allow an individual whose fee waiver request is denied to either pay the fee or resubmit a new fee waiver request within 10 days before the BIA or an immigration judge will reject the filing as improper. *See, e.g.,* Cal. Govt. Code 68634(g) (''If an application [for a fee waiver] is denied in whole or in part, the applicant shall pay the court fees and costs that ordinarily would be charged, or make the partial payment as ordered by the court, within 10 days after the clerk gives notice of the denial, unless within that time the applicant submits a new application'').

[14] The DHS, Immigration and Customs Enforcement (''ICE''), Office of the Principal Legal Advisor currently accepts electronic service through their eService portal. For more information, please visit *https://eserviceregistration.ice.gov/.*

in electronic filing, EOIR will continue to serve EOIR-generated documents in person or by mail on that party.

In order for EOIR to effectuate electronic service, the parties must maintain a valid email address within the eRegistry application. If a user's email address changes, the user must immediately update the relevant eRegistry account and file a new Form EOIR–27 or EOIR–28, as applicable, in each case with the updated email address. EOIR will consider service completed when the electronic notification is delivered to the last email address on file provided by the user, similar to the existing paper mail service provision for Notices to Appear and hearing notices. *Cf.* INA 239(c), 8 U.S.C. 1229(c) (''Service by mail under this section shall be sufficient if there is proof of attempted delivery to the last address provided by the alien . . . .'').

C. Signatures

This rulemaking proposes to provide standards for signatures. With this proposed rule, EOIR proposes to allow four types of signatures, depending on the document being filed and the method by which the document is being filed: (1) Original, handwritten ink signatures; (2) encrypted, digital signatures; (3) electronic signatures; and (4) conformed signatures.[15] Thus, this proposed rule would incorporate existing EOIR policy regarding signatures, Policy Memorandum 20–11, *Filings and Signatures* (Apr. 3, 2020), *https://www.justice.gov/eoir/page/file/1266411/download* (last visited Nov. 19, 2020), while also allowing conformed signatures in certain circumstances.

First, EOIR proposes to accept documents with original, handwritten ink signatures, encrypted digital signatures, or electronic signatures, whether filing electronically or on paper. If filed electronically, the document may be signed with an encrypted, digital signature; an electronic signature; or an original, handwritten ink signature and then scanned for upload to the electronic filing application. If a user signs a document using an encrypted digital signature but EOIR's electronic filing application is unavailable, the user may print the document with the digital signature and paper file the document with the immigration court.

Second, EOIR proposes to allow users to sign their own name with a conformed signature on documents filed through EOIR's electronic filing application. Conformed signatures will not be accepted for anyone other than the user who is submitting the document. Conformed signatures typically consist of the user typing ''/s/'' and the user's name into the signature block. For example: ''*/s/John Smith*.'' By signing into the electronic filing application, the user has demonstrated that they have completed identity verification through the eRegistry process described in Section III.A.2., thereby allowing the use of a conformed signature. EOIR seeks public comment as to whether this safeguard, which employs all Department-mandated information security protocols, is sufficient, whether there are other more effective methods for identity-proofing online filers who do not have the same financial or U.S. ''footprint'' that can be used for remote verification of the person's identity, or whether the user should need to re-input credentials at the time of each electronic filing.

These proposed signature rules would be subject to any specific form, application, or document signature requirements. For example, if an application's instructions require an original, handwritten ink signature, then the user must follow the application instructions instead of the proposed signature allowances in this proposed rule. In practice, if the user was electronically filing, the user would sign the application in ink and then scan and electronically file the application with EOIR. The user would also be required to make the original available upon request.

D. Electronic Payments

EOIR imposes a fee for filing many types of documents. *See generally* 8 CFR 1103.7. Currently, the immigration courts do not directly accept fee payments for any documents that require a fee. Instead, filers must make these fee payments to DHS and then provide proof of the payment to the immigration courts. This proposed rule does not change this payment structure at the immigration courts. Under this proposed rule, electronic filers would be able to submit a scanned copy of the filing fee receipt as part of their electronic submission.

In contrast, the BIA directly accepts payments for certain documents that require a fee. *See generally* 8 CFR 1003.8. In October 2020, EOIR launched the EOIR Payment Portal, which allows users to make electronic payments for filings at the BIA, as provided in 8 CFR 1003.8. *See* EOIR, *EOIR Payment Portal* (Nov. 19, 2020), *https://epay.eoir.justice.gov/*. As a result, this rulemaking proposes to broaden the references to payments at the BIA in 8 CFR 1003.2 and 1003.3 in order to account for these changes.

E. Duplicate Copies

This rulemaking proposes to update 8 CFR 1003.23 to remove the requirement for parties to file multiple ''in duplicate'' copies of a motion to reopen or a motion to reconsider if they are filing electronically. However, in duplicate copies would still be required for paper filings.

F. Technical Amendments

When updating existing regulatory sections, this rulemaking also proposes a number of technical amendments. These include updating outdated references from ''the Service,'' ''Service counsel,'' and ''Office of the District Counsel'' to ''DHS,'' ''DHS counsel,'' and ''ICE Office of the Principal Legal Advisor'' in 8 CFR 1001.1, 1003.1, 1003.2, 1003.3, 1003.23, 1003.31, 1214.2, 1240.2, 1240.10, 1240.11, 1240.13, 1240.26, 1240.32, 1240.33, 1240.48, 1240.49, 1240.51, 1245.21, and 1246.5, and lowercasing terms ''Immigration Judge'' and ''Immigration Court'' in 8 CFR 1003.2, 1003.17, 1003.23, 1003.31, 1003.32, 1003.37, 1003.38, and 1208.4 consistent with regulatory style guidelines. The rulemaking also proposes to update a reference at 8 CFR 1003.1(f) regarding service on a representative from part 292, which is a DHS regulation, to part 1292, which is an EOIR regulation.

IV. Regulatory Requirements

A. Regulatory Flexibility Act

The Department has reviewed this proposed rule in accordance with the Regulatory Flexibility Act and has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b). As proposed, this rulemaking regulates attorneys and accredited representatives, most of whom qualify as ''small entities'' under the Regulatory Flexibility Act. *See* 5 U.S.C. 601(3)–(4), (6). However, all attorneys and

[15] Digital signatures are defined as signatures performed via a recognized system that provides Personal Key Infrastructure (PKI) from the signer at the time of signing. EOIR Policy Memorandum 20–11, *Filings and Signatures* (Apr. 3, 2020), *https://www.justice.gov/eoir/page/file/1266411/download* (last visited Nov. 19, 2020). Electronic signatures are defined as signatures performed using a device that does not provide PKI at the time of signing (*e.g.,* stylus and touchpad). *Id.* at 1 n.2. Any type of signature—wet, digital, or electronic—may be subject to a challenge in immigration proceedings to its authenticity, though EOIR expects that any such challenge will be brought only in good faith. *Id.* at 2. Additionally, any type of signature may be authenticated, as necessary, using any means identified in Federal Rule of Evidence 901. *Id.*

accredited representatives already are required to enroll in eRegistry in order to practice before EOIR. Thus, they are already eligible to participate in the electronic filing process, which is currently being made available in many locations through a voluntary pilot program. This proposed rule, when finalized, would make the use of electronic filing mandatory in eligible cases.

The Department anticipates that the adoption of electronic filing will lead to substantial net cost savings for these attorneys and accredited representatives because they would no longer be required to bear the burdens and expenses of mailing or serving paper copies in each of their cases for filings submitted to the immigration court or to the BIA or for service of process on opposing counsel. Therefore, this proposed rule will not have an adverse economic effect on attorneys or accredited representatives, but instead is expected to result in significant cost savings. A more detailed analysis of the costs and benefits of this proposed rule are detailed in Section IV.D.

B. Unfunded Mandates Reform Act of 1995

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

C. Congressional Review Act

This proposed rule is not a major rule as defined by section 804 of the Congressional Review Act. 5 U.S.C. 804(2). This proposed 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 on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

D. Executive Order 12866 and Executive Order 13563 (Regulatory Planning and Review)

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). The Office of Information and Regulatory Affairs of the Office of Management and Budget (''OMB'') has determined that this proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866. It will neither result in an annual effect on the economy greater than $100 million nor adversely affect the economy or sectors of the economy. It does not pertain to entitlements, grants, user fees, or loan programs, nor does it raise novel legal or policy issues. It does not create inconsistencies or interfere with actions taken by other agencies. Accordingly, this proposed rule is not a significant regulatory action subject to review by OMB pursuant to Executive Order 12866.

Executive Order 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, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of using the best available methods to quantify costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Department certifies that this regulation has been drafted in accordance with the principles of Executive Order 13563.

1. ECAS-Related Costs and Savings

The Department estimates that implementation of ECAS will result in a total savings of $68,105,250 over the first 10 years of its implementation.[16] Specifically, the Department estimates that electronic filing will cost EOIR $32,896,179 over 10 years, primarily due to increased technology costs to implement and maintain the new technology infrastructure. These costs are outweighed, however, by the predicted savings to the public—$101,001,429, which primarily relate to cost savings from no longer having to file documents via mail or in person. These costs and savings for EOIR and the public are discussed in further detail individually below.

[16] All dollar amounts cited in this discussion are calculated to correspond with what would have been the value in December 2016 using the U.S. Bureau of Labor Statistics (BLS) Consumer Price Index inflation calculator found at *https://www.bls.gov/data/inflation_calculator.htm (last visited Nov. 19, 2020).*

TABLE 1—OVERVIEW OF TOTAL COST AND SAVINGS: EOIR AND THE PUBLIC [17]

Entity	Savings/costs
EOIR	($32,896,179)
OCIJ	12,910,888
BIA	2,710,950
OIT	(51,275,937)
OGC	2,757,920
Public	101,001,429
Total	68,105,250

Despite the financial cost to EOIR to develop and maintain the technology for ECAS, the Department believes that electronic filings will be a net benefit for the agency. During the electronic filing pilot program, EOIR has already begun to realize efficiencies in case processing. For example, in Fiscal Year (''FY'') 2019 DHS initiated 37,074 cases electronically (out of 465,790 cases initiated in the same time period), and 161 bond proceedings were initiated electronically. According to internal pilot metrics, charging documents filed electronically at the pilot sites are being processed nearly 10 times faster than charging documents filed in paper. Similarly, the time it takes to receive and process a non-charging supporting document is approximately 25 percent faster than processing a paper-filed supporting document. This represents a significant savings in terms of court staff time and in terms of the overall processing time for the 2,574 electronically filed motions that EOIR has received during the ECAS pilot program. This proposed rule will only increase these time savings when all attorneys and accredited representatives begin filing documents electronically.

a. Office of the Chief Immigration Judge

The Department estimates that implementation of the proposed rule will reduce the immigration courts' costs by the equivalent of approximately $12.9 million over the first 10 years of implementation. This reduction includes the cost of labor that will be reallocated to other tasks due to the more efficient processing of electronic documents. Cost changes for the courts will be realized primarily in initial case processing; individual hearing processing; and processing and shipping costs for changes of venue, appeals, and records retirement.

To reach its estimates, the Department determined the costs for adjudicating a

[17] Savings listed are an overestimation as they include all filings, rather than only those filings that can be done electronically at this time (*i.e.,* the savings include filings by *pro se* respondents who cannot yet use ECAS).

typical case after the implementation of the proposed regulation. Using this methodology, the Department identified and analyzed three separate scenarios: (1) Legacy paper ROPs that were started but not completed before this proposed rule; (2) eROPs for *pro se* respondents that are submitted in paper and scanned by court staff; and (3) eROPs for represented respondents that are completely electronic.

The Department then estimated the economic impact of the proposed regulation on the immigration courts for each of the next 10 years by calculating the average costs for each of the three scenarios above; multiplying each scenario's average cost by the expected annual number of cases received for the immigration courts and expected annual hearings for the immigration courts in each scenario over the next decade; separately calculating the baseline cost (*i.e.,* the cost without mandatory electronic filing), using existing time estimates and labor rates, for the next 10 years; and subtracting the post-regulation cost from the baseline cost for each of the next 10 years.

This economic impact reflects labor hours that will be saved in terms of dollars. In actuality, labor can be reallocated to higher-impact tasks, and more efficient labor usage could offset future hiring and resource needs, which may lead to more quantifiable realized savings. As shown in Table 2, the expected cost savings increase every year. This is a result of legacy paper ROPs leaving the system as cases are adjudicated and a higher percentage of the future pending cases having mandatory eROPs as a result of this regulation.

TABLE 2—OFFICE OF THE CHIEF IMMIGRATION JUDGE COST SAVINGS

Year	Expected cost savings
1	$140,304
2	526,622
3	816,841
4	1,115,708
5	1,320,399
6	1,500,104
7	1,666,355
8	1,816,269
9	1,947,925
10	2,060,361
Total	12,910,888

Since all paper-filed documents, per this new regulation, will be scanned and maintained in an eROP, initial case processing is estimated to become marginally more expensive as court staff must scan the paper documents into the eROP. However, this increase in cost will be outweighed by the time savings, calculated in terms of the cost of labor, for individual hearing processing and change of venue processing, as filing becomes more expeditious for court staff in each individual case. Additionally, annual shipping costs will be reduced, since changes of venue, appeals, and records retirement transfers will occur electronically instead of manually shipping the paper ROP to another court, the BIA, or the Federal Records Center.

Cost changes have been calculated with the assumption that all other processes remain the same. However, eROPs enable the possibility of further cost savings through more efficient case adjudication. For example, widely available eROPs may enable immigration judges to hear a case via video teleconference (''VTC'') almost instantly. Under the current paper ROP system, the ROP needs to be shipped to the immigration judge's location before a VTC hearing can be held. In contrast, an eROP could enable a judge to open any eROP and hear a case immediately. This new paradigm has the potential to improve the efficiency of workload adjudication by judges and their staff.

EOIR may also realize savings through the reduced growth of storage requirements at court locations. EOIR currently stores paper ROPs at immigration courts, utilizing valuable storage space in courtrooms, offices, and hallways. Conversion to an eROP system may ease the strain on the system as new pending cases will have an eROP that will not require physical storage space. With the information currently available, storage space utilization and savings cannot be specifically calculated. However, this regulation will likely reduce costs for the immigration courts by allowing current space to be used for functional purposes, rather than storage.

b. Board of Immigration Appeals

The Department also estimates that implementation of the proposed regulation will reduce the BIA's costs by approximately $2.7 million over the first 10 years of implementation. Cost changes for the BIA will be realized in three main process areas: Scanning *pro se* ROPs; receiving ROPs from the immigration courts; and returning ROPs to the immigration courts.

TABLE 3—BIA COSTS SAVINGS

Year	Expected cost savings
1	($23,064)
2	176,822
3	201,808
4	250,818
5	285,414
6	314,243
7	342,112
8	367,098
9	388,240
10	407,459
Total	2,710,950

The impacts to the BIA largely mirror the immigration courts in that scanning paper filings into the eROP is likely to increase costs by increasing staff workload. Further, the largest cost savings are likely to come from reduced shipping. The BIA's process requires that all ROPs sent to the BIA from the immigration court must be shipped back to the court upon completion of the appeal. Shipping costs will be eliminated for future eROPs because they will be transferred electronically, reducing costs for the BIA.

c. Office of Information Technology

The Department estimates that the implementation of the proposed rule will increase EOIR's Office of Information Technology's (''OIT'') costs by a total of approximately $51.3 million across the first 10 years of implementation. These costs are due to the additional effort required to develop, deploy, and maintain the electronic infrastructure that serves as the backbone for electronic filing.

Because OIT developed the tools and processes necessary for the implementation of mandatory electronic filing throughout EOIR, it is the largest driver of quantifiable costs from mandatory electronic filing implementation. The deployment and training for mandatory electronic filing will be particularly resource-intensive for OIT, as it will be responsible for the deployment and maintenance of the hardware and software necessary to digitize and store documents along with delivering training to court staff. Costs related to electronic filing deployment are estimated to be approximately $21.7 million, including $2.3 million in hardware purchases, $1.7 million in travel to deliver training and install systems, and $3.4 million in external services, software, and licensing for necessary cloud computing services.

TABLE 4—OIT ELECTRONIC FILING DEPLOYMENT COSTS

Category	Year 1	Year 2	Total
External Services (*e.g.,* MS Azure Premier Access)	$999,429	$999,429	$1,998,858
Software	625,988	726,171	1,352,159
Travel	830,295	830,295	1,660,590
Labor/Hardware [18]	11,316,689	5,355,028	16,671,717
Support Labor:			
Program Support	1,717,020	900,298	2,617,318
Training	754,782	431,820	1,186,602
Service Desk/Operations	482,417	482,417	964,834
Product Labor:			
eROP	2,699,130	1,322,681	4,021,811
Electronic Filing	3,741,362	1,833,416	5,574,778
Hardware	1,921,978	384,396	2,306,374
Total	13,772,401	7,910,923	21,683,324

Costs are estimated to be highest in the first year of the deployment, as hardware is purchased, software systems are finalized and implemented, and training is delivered to court staff. Costs are estimated to decrease by over 40 percent in the second deployment year as OIT completes training court staff and transitions to a steady state of software and hardware maintenance. The cost reductions in the second year of deployment will be driven by a 47 percent reduction in labor costs and an 80 percent reduction in hardware costs.

Once training and deployment are complete, OIT's costs will stabilize. While OIT will no longer incur costs related to training court staff, OIT will be using more labor than before mandatory electronic filing. This is due to the additional staff necessary to provide help desk support to the courts and IT services related to the electronic filing system. OIT will also continually accrue expenses for cloud computing platform licensing and hardware repairs, upgrades, and replacements required to support electronic filing. OIT estimates that overall costs will increase by approximately 1 percent each year, primarily driven by increases in labor costs. These ongoing expenses will represent the new steady state for OIT. The eight years following completion of the deployment phase are estimated to cost an additional $29.6 million due to mandatory electronic filing.

TABLE 5—OIT ELECTRONIC FILING STEADY STATE COSTS

Category	Year 3	Year 4	. . . [19]	Year 10	Total
External Services (*e.g.,* MS Azure Premier Access)	$999,429	$999,429		$999,429	$7,995,430
Software	366,521	366,521		366,521	2,932,169
Travel	0	0		0	0
Labor/Hardware	2,227,541	2,255,993		2,443,930	18,665,013
Support Labor:					
Program Support	239,564	239,564		239,564	1,916,512
Training	172,728	172,728		172,728	1,381,825
Service Desk/Operations	482,417	482,417		482,417	3,859,334
Products Labor:					
eROP	466,808	480,812		573,312	4,150,211
Electronic Filing	481,628	496,076		591,513	4,281,966
Electronic Filing Hardware	384,396	384,396		384,396	3,075,166
Total	3,593,491	3,621,943		3,809,880	29,592,613

As mandatory filing is implemented and electronic filing progresses, the Department anticipates that this will lead to significant additional efficiencies in case processing. This may include more expeditious case scheduling and adjudication, improved data quality, increased performance monitoring and tracking, augmented data analytics capabilities, and better alignment with information storage best practices. There may also be further impacts to EOIR's internal data-informed decision-making process, as the digitization of the data may allow for increased analysis of the relationship between various practices, procedures, and outcomes.

d. Office of General Counsel

The Department estimates that the implementation of the proposed rule will increase efficiencies for the EOIR Office of the General Counsel (''OGC'') programs. For example, digitization of files will allow for more expeditious compliance with Freedom of Information Act (''FOIA'') and other requests for information, reducing the time burden of such activities on EOIR staff. Specifically, the Department estimates that costs associated with FOIA compliance will decrease by approximately $2.8 million across the first 10 years of implementation. These savings will be realized through reduced shipping costs in the FOIA response process as more ROPs are accessible

[18] Labor/Hardware represents a total of the individual categories of support labor, product labor, and hardware.

[19] Years 5 through 9 are not included in this visual, but are factored into the totals calculation. OIT estimates that labor costs will increase by 3 percent per year. Non-labor costs, such as hardware, software, and external services, remain constant through each year.

electronically instead of requiring storage retrieval and shipping.

As electronic filing becomes more widespread, the proportion of FOIA requests that can be satisfied through electronic records searches will proportionally increase. A higher percentage of the future pending caseload will have mandatory eROPs as a result of this regulation, which will cause the ratio of eROPs to paper ROPs, and thus expected cost savings, to increase over time, as detailed in Table 6.

TABLE 6—OGC COST SAVINGS

Year[20]	Expected cost savings
1	$0
2	0
3	60,052
4	203,084
5	295,661
6	360,279
7	404,478
8	443,370
9	479,318
10	511,678
Total	2,757,920

The public may also see the added qualitative benefit of more expeditious FOIA compliance, as OGC will not have to wait for records to be shipped between locations to satisfy FOIA requests and will instead be able to search and access the records electronically.

e. The Public

The benefits to the public are high as well. Parties will be able to file documents at any time of day from any location with internet, thereby reducing postage costs and the need to physically appear at an immigration court during business hours. For many parties, this will be a substantial benefit, as the nearest immigration court may be hours away. The parties will also be able to view the eROP electronically, providing instant access to necessary documents and eliminating the need to appear at the immigration court to view the paper record. Further, parties will save on paper and toner costs required to print copies of filings, and costs associated with required process service.

The Department believes that the biggest savings to the parties before EOIR will be from reduced costs associated with mailing or hand-delivering filings that would have been incurred without the implementation of electronic filing. In FY 2018, EOIR's immigration courts received 311,761 paper filings and 2,555 electronic filings,[21] and the BIA received 49,522 paper filings.[22] While EOIR does not keep data regarding what methods (*e.g.,* Federal Express (''FedEx''), United States Postal Service (''USPS''), hand delivery by an attorney's office or a *pro se* party, or local courier) are used to file paper documents with EOIR and to serve those filings on the opposing party, anecdotal evidence points to filings with the immigration courts and the BIA and service on the opposing party typically being sent using FedEx or courier to ensure filings are timely. This is particularly true for filings with the BIA, because the filer must ensure actual receipt by the BIA in Falls Church, Virginia no later than the close of business of the clerk's office on the established deadline.

To analyze the cost savings related to these filings that electronic filing would have on the public, EOIR considered the average costs of sending filings through FedEx and USPS, the hourly rates for couriers and immigration attorneys, and the time savings from avoiding use of the immigration courts' intra-office mailing systems. Based on these preliminary estimates and filings from the previous year, if filers used FedEx for one-third of filings and used USPS for two-thirds of filings, electronic filing would have saved filers $38,778.55 in FedEx and USPS costs in the five pilot courts in FY 2018.[23] This is compared to a cost of $1,959,360.15 in FedEx costs[24] and $2,772,396.55 in USPS filing costs[25] (assuming one-third filings via FedEx and two-thirds filings via USPS) in the other 55 courts. These estimates are based on an $18.85 average FedEx filing rate ($8.57 average Express Saver cost + $20.03 average second day cost + $27.97 overnight cost, divided by three) and a $13.34 average USPS filing rate ($7.75 average priority mail + $28.59 average priority mail express + $3.68 first-class parcel, divided by three). The Department notes that this savings is likely an underestimate due to the tendency for many filers to use next day service.

According to the U.S. Bureau of Labor Statistics, the mean hourly wage for couriers, such as those the individuals law firms may hire to delivery documents to the immigration court, is $14.13. U.S. Bureau of Labor Statistics, *Occupational Employment Statistics: Occupational Employment and Wages, May 2018: 43–5021 Couriers and Messengers, https://www.bls.gov/oes/2018/may/oes435021.htm* (last updated Mar. 29, 2019).[26] Further, if an attorney makes the trip to the immigration court or to the BIA to handle the filing, the average cost would be $66.54 for one hour of work.[27] Assuming that approximately one-quarter of paper filings are handled via a courier, one-quarter of paper filings are handled via an attorney,[28] and one-half are filed using USPS or FedEx, with two-thirds of those via USPS and one-third via FedEx, the cost savings to the public of eFiling in the five pilot courts was approximately $70,917.24 ($8,028.85 for FedEx[29] + $11,360.42 for USPS[30] + $42,502.43 for the attorneys[31] + $9,025.54 for the couriers[32]).

Overall, the Department's estimates predict an annual savings to the public from electronic filing before the immigration courts and the BIA of approximately $10,100,142.88 ($70,917.24/2,555 filings = $27.76; $27.76 * (311,761 + 2,555 + 49,522 = 363,838 total filings)). Over the course of 10 years, these savings would equal $101,001,428.80 if the annual number of filings remains constant. The Department, however, expects that the true savings will be higher as EOIR hires additional immigration judges and

[20] FOIA volume is estimated at 50,000 per year, an approximation based on EOIR's FY 2018 FOIA volume.

[21] These numbers represent the paper and electronic filing of initial Forms I–862, Notice to Appear, and I–863, Notice of Referral to the Immigration Judge, by DHS at the immigration courts nationwide for the fiscal year. EOIR does not have data regarding the number of paper vs. electronic filings directly by aliens in proceedings or their representatives, such as the relative number of paper vs. electronically filed motions, applications for relief or protection, or evidence packets. Accordingly, this analysis uses the number of electronic and paper filings by DHS as a proxy for those by the aliens and their representatives since EOIR does not have similar data for that population but would expect the percentage of paper and electronic to be the same for both.

[22] *See* EOIR, *Statistics Yearbook: Fiscal Year 2018* (Aug. 30, 2019), *https://www.justice.gov/eoir/file/1198896/download* (last visited Nov. 19, 2020). As with the immigration courts, the Department uses the number of cases filed at the BIA as a proxy for the number of filings at the BIA because the Department does not have specific data regarding the number of individual filings by the parties.

[23] 852 filings * $18.85 average FedEx cost + 1,703 filings * $13.34 average USPS cost.

[24] 103,920 filings * $18.85 average FedEx cost.

[25] 207,841 filings * $13.34 average USPS cost.

[26] $14.72 in May 2018 is equivalent to $14.13 in December 2016.

[27] U.S. Bureau of Labor Statistics, *Occupational Employment Statistics: Occupational Employment and Wages, May 2018: 23–1011 Lawyers, https://www.bls.gov/oes/2018/may/oes231011.htm* (last visited Nov. 19, 2020) (stating the mean hourly wage in May 2018 was $69.34). $69.34 in May 2018 is equivalent to $66.54 in December 2016.

[28] This calculation further assumes that the filings would require one hour of time by the attorney or courier.

[29] 426 filings * $18.85 average FedEx cost.

[30] 852 filings * $13.34 average USPS cost.

[31] 639 filings * $66.54 mean hourly attorney wage.

[32] 639 filings * $14.13 mean hourly courier wage.

opens additional immigration courts, expanding the annual case processing capacity. *See, e.g.,* EOIR, Executive Office for Immigration Review Adjudication Statistics: New Cases and Total Completions (Oct. 13, 2020), *https://www.justice.gov/eoir/page/file/1060841/download* (last visited Nov. 19, 2020) (showing that initial case completions increased from 195,106 in FY 2018 to 276,918 in FY 2019). Further, additional savings are expected based on gas and tolls, paper, toner, and other office supplies.

TABLE 7—COST AND SAVINGS FOR PUBLIC (FY18) [33]

FedEx envelope rates [34]	FedEx express saver	FedEx 2 day	FedEx standard overnight
FedEx Local (0–150 miles)	$7.64	$17.83	$23.53
FedEx Regional (151–600 miles)	8.16	19.34	25.80
FedEx National (601+ miles)	9.90	22.92	34.57
Average Cost	8.57	20.03	27.97
Costs of ⅓ OCIJ Paper Filings (103,920)	890,250.86	2,081,524.28	22,906,305.32
Total Costs of ⅓ BIA Paper Filings (16,507)	141,412.82	330,641.89	461,655.09
Savings from eFilings (2,555)	21,887.83	51,176.65	71,454.83
USPS rates by zone [35]	**Priority mail [36]**	**Priority express [37]**	**First-class parcel [38]**
USPS Zone 1&2 (0–150 miles)	$6.95	$24.43	$3.52
USPS Zone 3 (151–300 miles)	7.28	24.66	3.57
USPS Zone 4 (301–600 miles)	7.42	25.50	3.62
USPS Zone 5 (601–1,000 miles)	7.65	28.47	3.66
USPS Zone 6 (1,001–1,400 miles)	7.83	30.37	3.71
USPS Zone 7 (1,401–1,800)	8.21	32.27	3.76
USPS Zone 8 (1,801+)	8.90	34.45	3.89
Average Cost	7.75	28.59	3.68
Costs of ⅔ OCIJ Paper Filings (207,841)	1,610,468.25	5,942,758.49	763,962.91
Costs of ⅔ BIA Paper Filings (16,507)	255,816.50	943,983.65	121,352.48
Savings from eFilings (2,555)	19,767.6	73,054.75	9,391.45

Documents will also be served by electronic notification where applicable, which will provide near-instantaneous service. This will particularly benefit the parties when EOIR electronically serves orders and decisions on parties participating in electronic filing, as the appeal clock begins to run when the order is sent. This will allow the parties to begin preparing for any potential appeals immediately without having to wait for the order or decision to arrive in the mail as is currently the practice.

These potential benefits are reflected in the private bar's long-standing requests for electronic filing with EOIR. *See, e.g.,* EOIR, *EOIR/AILA Liaison Meeting* (Sept. 26, 2002), *https://www.justice.gov/eoir/eoir-aila-sep26-2002.* (last visited Nov. 19, 2020). In addition, since the July 2018 launch of the electronic filing pilot program, more than 15,000 attorneys have signed up for ECAS, indicating a strong interest in electronic filing. Moreover, at the pilot sites, approximately half of all active attorneys and accredited representatives in those sites have signed up for the pilot despite having no obligation to participate.

2. Costs and Savings Related to Rules Regarding Law Student and Law Graduate Filings

This rulemaking also proposes changes to law student and law graduate filing and accompaniment rules. First, EOIR believes that there will be minimal, if any, costs associated with requiring the supervisor to electronically file documents with EOIR, rather than the law student or law graduate filing on paper. And, if there are any associated costs, they will be outweighed by the substantial benefits of electronic filing, including immediate access to the eROP and the ability to file at any time of day from any location with internet access without the cost or reliance on mail carriers.

As to the proposed accompaniment change, EOIR does not maintain data on how many law students appear in immigration court or how many of those appear without a supervisor present, though it understands that in most cases, a supervisor does accompany the law student. Moreover, regardless of EOIR's rules, in many cases a supervisor is required to accompany the law student or graduate in order to comply with applicable state bar rules. *See, e.g.,* Cal. R. 9.42(d)(3) (allowing certified California law students to appear ''on behalf of the client in any public trial, hearing, arbitration, or proceeding, or before any arbitrator, court, public agency, referee, magistrate, commissioner, or hearing officer, to the extent approved by such arbitrator, court, public agency, referee, magistrate, commissioner, or hearing officer,'' provided that, among other requirements, the certified law student ''[p]erforms the activity under the direct

[33] In order to estimate these costs for the public, the Department looked to FedEx and USPS rates as a general representation for the costs of paper filing via mail or delivery service as they are the two most commonly used delivery services for filings with the Department.

[34] *See* FedEx, *FedEx One Rate Pricing* (effective Jan. 7, 2019), *available at https://www.fedex.com/content/dam/fedex/us-united-states/services/OneRate-Pricing_2019.pdf* (last visited Nov. 19, 2020). As noted, *supra,* in Footnote 16, these FedEx prices have been discounted to reflect their values as of December 2016.

[35] This chart does not include the USPS rates for zone 9 as there are no immigration court locations in the Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands. *See* USPS Office of Inspector General, *Audit Report Management of Postal Zones,* at 4 (March 25, 2019), *available at https://www.uspsoig.gov/sites/default/files/document-library-files/2020/19RG009MS000-20.pdf* (last visited Nov. 19, 2020).

[36] These rates correspond with the USPS priority mail rates for letters, large envelopes, and parcels that do not exceed one pound.

[37] These rates correspond with the USPS priority mail express rates for letters, large envelopes, and parcels that do not exceed 0.5 pound.

[38] These rates correspond with the USPS first class package service rates for retail parcels that do not exceed one ounce.

and immediate supervision and in the personal presence of the supervising attorney'').

EOIR recognizes that in rare cases in which a law school clinic or similar program does not currently send a supervising attorney to every hearing at which a law student or law graduate appears, there may be some increased cost. EOIR expects those increased costs to be minimal, however, due to the rarity of cases in which law students and law graduates appear unsupervised, as well as the availability of telephonic appearances.[39] Further, EOIR believes that the benefits of ensuring that every case has a single licensed representative responsible for service of process and ultimate representation in the case outweighs the potential costs associated with the increased accompaniment requirements.[40]

E. Executive Order 13132 (Federalism)

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this proposed 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 proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

G. Paperwork Reduction Act

This rulemaking does not propose new or revisions to existing ''collection[s] of information'' as that term is defined in the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320.

List of Subjects

8 CFR Part 1001

Administrative practice and procedure, Immigration.

8 CFR Part 1003

Administrative practice and procedure, Immigration.

8 CFR Part 1208

Administrative practice and procedure, Aliens, Immigration, Reporting and recordkeeping requirements

8 CFR Part 1214

Administrative practice and procedure, Aliens.

8 CFR Part 1240

Administrative practice and procedure, Immigration.

8 CFR Part 1245

Aliens, Immigration, Reporting and recordkeeping requirements.

8 CFR Part 1246

Administrative practice and procedure, Aliens, Immigration.

8 CFR Part 1292

Administrative practice and procedure, Immigration.

Accordingly, for the reasons set forth in the preamble, and by the authority vested in the Director, Executive Office for Immigration Review, by the Attorney General Order Number 410–2020, the Department proposes to amend parts 1001, 1003, 1208, 1214, 1240, 1245, 1246, and 1292 of the Code of Federal Regulations as follows:

PART 1001—DEFINITIONS

■ 1. The authority citation for part 1001 continues to read as follows:

Authority: 5 U.S.C. 301; 8 U.S.C. 1101, 1103; Pub. L. 107–296, 116 Stat. 2135; Title VII of Pub. L. 110–229.

■ 2. Amend § 1001.1 by revising paragraph (s) and adding paragraphs (cc), (dd), and (ee) to read as follows:

§ 1001.1 Definitions.

* * * * *

(s) The terms *government counsel* or *DHS counsel,* in the context of proceedings in which DHS has appeared, mean any officer assigned to represent the DHS in any proceeding before an immigration judge or the Board of Immigration Appeals.

* * * * *

(cc) The term *case eligible for electronic filing* means any case that DHS seeks to bring before an immigration court after EOIR has formally established an electronic filing system for that court, or any case before an immigration court or the Board of Immigration Appeals that has an electronic record of proceeding. Any reference to a record of proceeding in this chapter shall include an electronic record of proceeding.

(dd) The term *filing* means the actual receipt of a document by the appropriate immigration court or the Board of Immigration Appeals.

(1) An electronic filing that is accepted by the Board or an immigration court will be deemed filed on the date it was submitted. A paper filing that is accepted by the Board or an immigration court will be deemed filed on the date it was received by the Board or the immigration court. A filing that is rejected by the Board or the immigration court as an improper filing will not be deemed filed on the date it was submitted or received.

(2) For purposes of paragraph (dd)(1) of this section, an improper filing includes, but is not limited to:

(i) If a fee is required, failure to submit a fee receipt or fee waiver request;

(ii) If a fee is required, the denial of a fee waiver request by the Board or an immigration judge, provided that the Board or immigration judge, in the adjudicator's discretion and no more than once per case, may, before rejecting a filing as improper under this paragraph, grant an individual whose fee waiver request is denied up to a maximum of 10 days to either pay the required fee or to file a new request if the initial request was incomplete or insufficient and may toll any applicable deadline by up to a maximum of 10 days accordingly;

(iii) Failure to include a proof of service upon the opposing party;

(iv) Failure to comply with the language, signature, and format requirements;

(v) Insufficient postage or incorrect courier billing information; or

(vi) Illegibility of the filing.

(vii) If a document is improperly filed but not rejected, the Board or immigration judge retains the authority to take appropriate action.

(ee) The term *service* means physically presenting, mailing, or

[39] Due to the current outbreak of COVID–19, many immigration judges have adopted standing orders allowing practitioners to appear by telephone without the need for filing a motion. *See Immigration Court Practice Manual,* at Appx. R. Although EOIR cannot predict how long such standing orders will remain in effect, it reiterates that nothing in this proposed rule precludes a law school clinic from filing a motion for a telephonic appearance in order to reduce the need for in-person appearances.

[40] Although most law school clinics and similar programs only take cases at immigrations courts that are located in nearby geographic proximity, both to minimize operational and logistical difficulties and to avoid the complications of complying with practice rules for different state jurisdictions, EOIR also recognizes that there may be unique situations in which a law school clinic takes a case that requires atypical travel arrangements. In that situation, coupled with the similarly unique situation of an unsupervised law student appearing alone on behalf of a respondent, EOIR acknowledges there may be an increase in cost associated with this rule, but the benefit of the rule outweighs any cost associated with this highly unlikely situation.

electronically providing a document to the appropriate party or parties; except that an Order to Show Cause or Notice of Deportation Hearing shall be served in person to the alien, or by certified mail to the alien or the alien's attorney, and a Notice to Appear shall be served to the alien in person, or if personal service is not practicable, shall be served by regular mail to the alien or the alien's attorney of record.

PART 1003—EXECUTIVE OFFICE FOR IMMIGRATION REVIEW

■ 3. The authority citation for part 1003 continues to read as follows:

Authority: 5 U.S.C. 301; 6 U.S.C. 521; 8 U.S.C. 1101, 1103, 1154, 1155, 1158, 1182, 1226, 1229, 1229a, 1229b, 1229c, 1231, 1254a, 1255, 1324d, 1330, 1361, 1362; 28 U.S.C. 509, 510, 1746; sec. 2 Reorg. Plan No. 2 of 1950; 3 CFR, 1949–1953 Comp., p. 1002; section 203 of Pub. L. 105–100, 111 Stat. 2196–200; sections 1506 and 1510 of Pub. L. 106–386, 114 Stat. 1527–29, 1531–32; section 1505 of Pub. L. 106–554, 114 Stat. 2763A–326 to –328.

■ 4. Amend § 1003.1 by revising paragraph (f) to read as follows:

§ 1003.1 Organization, jurisdiction, and powers of the Board of Immigration Appeals.

* * * * *

(f) *Service of Board decisions.* The decision of the Board shall be in writing. The Board shall transmit a copy to DHS and serve a copy upon the alien or the alien's representative, as provided in part 1292 of this chapter.

* * * * *

■ 5. Amend § 1003.2 by:

■ a. Revising the introductory text of paragraph (g);

■ b. Revising paragraphs (g)(1) and (g)(2)(i) through (iii); and

■ c. Adding paragraphs (g)(4) through (8).

The revisions and additions read as follows:

§ 1003.2 Reopening or reconsideration before the Board of Immigration Appeals.

* * * * *

(g) *Filing procedures.* This paragraph applies to the filing of documents related to reopening and reconsideration before the Board.

(1) *English language and entry of appearance.* A motion and any submission made in conjunction with a motion must be in English or accompanied by a certified English translation. If the moving party, other than DHS, is represented, Form EOIR–27, Notice of Entry of Appearance as Attorney or Representative Before the Board, must be filed with the motion.

(2) * * *

(i) A motion to reopen or motion to reconsider a decision of the Board pertaining to proceedings before an immigration judge shall be filed directly with the Board. Such motion must be accompanied by a payment in a manner authorized by EOIR or fee waiver request in satisfaction of the fee requirements of § 1003.8. The record of proceeding pertaining to such a motion shall be forwarded to the Board upon the request or order of the Board.

(ii) A motion to reopen or a motion to reconsider a decision of the Board pertaining to a matter initially adjudicated by an officer of DHS shall be filed with the officer of DHS having administrative control over the record of proceeding.

(iii) If the motion is made by DHS in proceedings in which DHS has administrative control over the record of proceedings, the record of proceedings in the case and the motion shall be filed directly with the Board. If such motion is filed directly with an office of DHS, the entire record of proceeding shall be forwarded to the Board by the DHS officer promptly upon receipt of the briefs of the parties, or upon expiration of the time allowed for the submission of such briefs.

* * * * *

(4) *Filing parties.* DHS and all alien attorneys and accredited representatives are required to electronically file all documents with the Board through EOIR's electronic filing application in all cases eligible for electronic filing. Although not required, unrepresented respondents, applicants, or petitioners, reputable individuals, and accredited officials may electronically file documents with the Board through EOIR's electronic filing application in cases eligible for electronic filing. An unrepresented individual, reputable individual, or accredited official who elects to use EOIR's electronic filing application shall be required to register in conformity with § 1292.1(f) as a condition of using that application. If an unrepresented respondent, applicant, or petitioner or reputable individual or accredited official opts to use EOIR's electronic filing application for a case, the individual must electronically file all documents with the Board for that case unless the Board, only upon a motion filed by the individual with good cause shown, grants leave to opt out of using the electronic filing application. An unrepresented individual, reputable individual, or accredited official who has been granted leave to opt out of using EOIR's electronic filing application for a case may not subsequently opt in again to use that application for the same case.

(5) *Filing requirements.* Parties must make the originals of all filed documents available upon request to the Board or the opposing party for review. If EOIR's electronic filing application is unavailable due to an unplanned system outage on the last day for filing in a specific case, then the filing deadline will be extended to the first day that the electronic filing application becomes accessible that is not a Saturday, Sunday, or legal holiday. For planned system outages, parties must electronically file documents during system availability within the applicable filing deadline or paper file documents within the applicable filing deadline. EOIR will issue public communications for planned system outages ahead of the scheduled outage. Any planned system outage announced three or fewer business days prior to the start of the outage will be treated as an unplanned outage. The Board retains discretion to accept paper filings in all cases.

(6) *Classified information.* Notwithstanding any other provision of this chapter, classified information is never allowed to be electronically filed.

(7) *Signatures.* All documents filed with the Board that require a signature must have an original, handwritten ink signature, an encrypted digital signature, or an electronic signature. Electronic filings submitted through EOIR's electronic filing application that require the user's signature may have a conformed signature. This paragraph is subject to the requirements of the application or document being submitted.

(8) *Service.* The service of filings with the Board depends on whether the documents are filed through EOIR's electronic filing application or in paper.

(i) *Service of electronic filings.* If all parties are using EOIR's electronic filing application in a specific case, the parties do not need to serve a document that is filed through EOIR's electronic filing application on the opposing party. EOIR's electronic filing application will effectuate service by providing a notification of all electronically filed documents on all parties by email. Upon successful upload by one of the parties, EOIR will email a notification to the email addresses provided in paragraph (g)(7)(ii) of this section. If one or more parties are not filing through EOIR's electronic filing application in a specific case, the parties must follow the service procedures in paragraph (g)(7)(iii) of this section.

(ii) *Valid Email Address.* Use of EOIR's electronic filing application

requires a valid email address for electronic service. The Board will use the email address provided through eRegistry for electronic service on participating parties. Users must immediately update their eRegistry account if their email address changes. Representatives must additionally file a new Form EOIR–27 with the Board if their email address changes. EOIR will consider service completed when the electronic notification is delivered to the last email address on file provided by the user.

(iii) *Service of paper filings.* If electronic filing is not being used in a particular case, the party filing with the Board must serve a copy of the filing on the opposing party and include a certificate of service showing service on the opposing party with their filing. If the moving party is not DHS, service of the motion shall be made upon the ICE Office of the Principal Legal Advisor for the field location in which the case was completed before the immigration judge.

* * * * *

■ 6. Amend § 1003.3 revising paragraphs (a)(2), (a)(3), and (c)(2) and adding paragraph (g) to read as follows:

§ 1003.3 Notice of appeal.

(a) * * *

(2) *Appeal from decision of a DHS officer.* A party affected by a decision of a DHS officer that may be appealed to the Board under this chapter shall be given notice of the opportunity to file an appeal. An appeal from a decision of a DHS officer shall be taken by filing a Notice of Appeal to the Board of Immigration Appeals from a Decision of a DHS Officer (Form EOIR–29) directly with the DHS office having administrative control over the record of proceeding within 30 days of the service of the decision being appealed. An appeal is not properly filed until it is received at the appropriate DHS office, together with all required documents, and the fee provisions of § 1003.8 are satisfied.

(3) *General requirements for all appeals.* The appeal must be accompanied by a payment in a manner authorized by EOIR or fee waiver request in satisfaction of the fee requirements of § 1003.8. If the respondent or applicant is represented, a Notice of Entry of Appearance as Attorney or Representative Before the Board (Form EOIR–27) must be filed with the Notice of Appeal. The appeal and all attachments must be in English or accompanied by a certified English translation.

* * * * *

(c) * * *

(2) *Appeal from decision of a DHS officer.* Briefs in support of or in opposition to an appeal from a decision of a DHS officer shall be filed directly with the DHS office having administrative control over the file. The alien and DHS shall be provided 21 days in which to file a brief, unless a shorter period is specified by the DHS officer from whose decision the appeal is taken, and reply briefs shall be permitted only by leave of the Board. Upon written request of the alien, the DHS officer from whose decision the appeal is taken or the Board may extend the period for filing a brief for good cause shown. The Board may authorize the filing of briefs directly with the Board. In its discretion, the Board may consider a brief that has been filed out of time. All briefs and other documents filed in conjunction with an appeal, unless filed by an alien directly with a DHS office, shall include proof of service on the opposing party.

* * * * *

(g) *Filing.* This paragraph applies to the filing of documents related to appeals before the Board.

(1) *Filing parties.* DHS and all attorneys and accredited representatives are required to electronically file all documents with the Board through EOIR's electronic filing application in all cases eligible for electronic filing. Although not required, unrepresented respondents, applicants, or petitioners, reputable individual, and accredited officials may electronically file documents with the Board through EOIR's electronic filing application in cases eligible for electronic filing. An unrepresented individual, reputable individual, or accredited official who elects to use EOIR's electronic filing application shall be required to register in conformity with § 1292.1(f) as a condition of using that application. If an unrepresented respondent, applicant, or petitioner, reputable individual, or accredited official opts to use EOIR's electronic filing application for a case, the individual must electronically file all documents with the Board for that case unless the Board, only upon a motion filed by the individual with good cause shown, grants leave to opt out of using the electronic filing application. An unrepresented individual, reputable individual, or accredited official who has been granted leave to opt out of using EOIR's electronic filing application for a case may not subsequently opt in to use that application for the same case.

(2) *Filing requirements.* Parties must make the originals of all filed documents available upon request to the Board or to the opposing party for review. If EOIR's electronic filing application is unavailable due to an unplanned system outage on the last day for filing in a specific case, then the filing deadline will be extended to the first day that the electronic filing application becomes accessible that is not a Saturday, Sunday, or legal holiday. For planned system outages, parties must electronically file documents during system availability within the applicable filing deadline or paper file documents within the applicable filing deadline. EOIR will issue public communications for planned system outages ahead of the scheduled outage. Any planned system outage announced three or fewer business days prior to the start of the outage will be treated as an unplanned outage. The Board retains discretion to accept paper filings in all cases.

(3) *Classified information.* Notwithstanding any other provision of this chapter, classified information is never allowed to be electronically filed.

(4) *Signatures.* All documents filed with the Board that require a signature must have an original, handwritten ink signature, an encrypted digital signature, or an electronic signature. Electronic filings submitted through EOIR's electronic filing application that require the user's signature may have a conformed signature. This paragraph is subject to the requirements of the application or document being submitted.

(5) *Service.* The service of filings with the Board depends on whether the documents are filed through EOIR's electronic filing application or in paper.

(i) *Service of electronic filings.* If all parties are using EOIR's electronic filing application in a specific case, the parties do not need to serve a document that is filed through EOIR's electronic filing application on the opposing party. EOIR's electronic filing application will effectuate service by providing a notification of all electronically filed documents on all parties by email. Upon successful upload by one of the parties, EOIR will email a notification to the email addresses provided in paragraph (g)(5)(ii) of this section. If one or more parties are not filing through EOIR's electronic filing application in a specific case, the parties must follow the service procedures in paragraph (g)(5)(iii) of this section.

(ii) *Valid Email Address.* Use of EOIR's electronic filing application requires a valid email address for electronic service. The Board will use the email address provided through eRegistry for electronic service on participating parties. Users must

immediately update their eRegistry account if their email address changes. Representatives must additionally file a new Form EOIR–27 with the Board if their email address changes. EOIR will consider service completed when the electronic notification is delivered to the last email address on file provided by the user.

(iii) *Service of paper filings.* If electronic filing is not being used in a particular case, the party filing with the Board must serve a copy of the filing on the opposing party and include a certificate of service showing service on the opposing party with their filing.

■ 7. Amend § 1003.13 by removing the ''Filing'' and ''Service'' definitions.

■ 8. Amend § 1003.17 by revising paragraph (a) to read as follows:

§ 1003.17 Appearances.

(a) In any proceeding before an immigration judge in which the alien is represented, the attorney or representative shall file a Notice of Entry of Appearance on Form EOIR–28 with the immigration court, and shall serve a copy of the Notice of Entry of Appearance on DHS as required by § 1003.32. The entry of appearance of an attorney or representative in a custody or bond proceeding shall be separate and apart from an entry of appearance in any other proceeding before the immigration court. An attorney or representative may file a Form EOIR–28 indicating whether the entry of appearance is for custody or bond proceedings only, any other proceedings only, or for all proceedings. Such Notice of Entry of Appearance must be filed and served even if a separate Notice of Entry of Appearance(s) has previously been filed with DHS for appearance(s) before DHS.

* * * * *

■ 9. Amend § 1003.23 by revising paragraph (b)(1)(ii) to read as follows:

§ 1003.23 Reopening or reconsideration before the immigration court.

* * * * *

(b) * * *

(1) * * *

(ii) *Filing.* Motions to reopen or reconsider a decision of an immigration judge must be filed with the immigration court having administrative control over the Record of Proceeding. If necessary under § 1003.32, a motion to reopen or a motion to reconsider shall include a certificate showing service on the opposing party of the motion and all attachments. If the moving party is not DHS, service of the motion shall be made upon the ICE Office of the Principal Legal Advisor for the field location in which the case was completed. If the moving party, other than DHS, is represented, a Form EOIR–28, Notice of Appearance as Attorney or Representative Before an Immigration Judge must be filed with the motion. If filed in paper, the motion must be filed in duplicate with the immigration court, accompanied by a fee receipt.

* * * * *

■ 10. Revise § 1003.31 to read as follows:

§ 1003.31 Filing documents and applications.

This section applies to the filing of all documents, including motions and applications, before the immigration courts.

(a) *Filing parties.* DHS and all attorneys and accredited representatives are required to electronically file all documents, including charging documents, with the immigration courts through EOIR's electronic filing application in all cases eligible for electronic filing. Although not required, unrepresented respondents or applicants, reputable individuals, and accredited officials may electronically file documents with the immigration courts through EOIR's electronic filing application in cases eligible for electronic filing. An unrepresented individual, reputable individual, or accredited official who elects to use EOIR's electronic filing application shall be required to register in conformity with § 1292.1(f) as a condition of using that application. If an unrepresented respondent or applicant, reputable individual, or accredited official opts to use EOIR's electronic filing application for a case, the individual must electronically file all documents with the immigration court for that case unless an immigration judge, only upon a motion filed by the individual with good cause shown, grants leave to opt out of using the electronic filing application. An unrepresented individual, reputable individual, or accredited official who has been granted leave to opt out of using EOIR's electronic filing application for a case may not subsequently opt in to use that application for the same case.

(b) *Filing requirements.* If EOIR's electronic filing application is unavailable due to an unplanned system outage on the last day for filing in a specific case, then the filing deadline will be extended to the first day that the electronic filing application becomes accessible that is not a Saturday, Sunday, or legal holiday. For planned system outages, parties must electronically file documents during system availability within the applicable filing deadline or paper file documents within the applicable filing deadline. EOIR will issue public communications for planned system outages ahead of the scheduled outage. Any planned system outage announced three or fewer business days prior to the start of the outage will be treated as an unplanned outage. In all other situations in cases eligible for electronic filing, an immigration judge may accept paper filings from a party otherwise required to file electronically, but only in open court and only:

(i) For rebuttal or impeachment purposes,

(ii) Upon good cause shown, provided that the filing is otherwise admissible and the immigration judge finds that any applicable filing deadline should be excused, or

(iii) When the opposing party does not object to the paper filing.

(c) *Originals.* Parties must make the originals of all filed documents available upon request to the immigration court or the opposing party for review.

(d) *Classified information.* Notwithstanding any other provision of this chapter, classified information is never allowed to be electronically filed.

(e) *Where to file.* All documents that are to be considered in a proceeding before an immigration judge must be filed with the immigration court having administrative control over the Record of Proceeding.

(f) *Fees.* Except as provided in § 1240.11(f), all documents or applications filed with the immigration courts requiring the payment of a fee must be accompanied by a fee receipt from DHS or a fee waiver application pursuant to § 1103.7(c). Except as provided in § 1003.8, any fee relating to immigration judge proceedings shall be paid to, and accepted by, any DHS office authorized to accept fees for other purposes pursuant to § 1103.7(a).

(g) *Filing deadlines.* The immigration judge may set and extend time limits for the filing of applications and related documents and responses thereto, if any. If an application or document is not filed within the time set by the immigration judge, the opportunity to file that application or document shall be deemed waived.

(h) *Filing under seal.* DHS may file documents under seal by including a cover sheet identifying the contents of the submission as containing information which is being filed under seal. Documents filed under seal shall only be examined by persons with authorized access to the administrative record.

(i) *Signatures.* All documents filed with the immigration courts that require

a signature must have an original, handwritten ink signature, an encrypted digital signature, or an electronic signature. Electronic filings submitted through EOIR's electronic filing application that require the user's signature may have a conformed signature. This paragraph is subject to the requirements of the application or document being submitted.

■ 11. Revise § 1003.32 to read as follows:

§ 1003.32 Service and size of documents.

The service of filings with the immigration courts depends on whether the documents are filed through EOIR's electronic filing application or in paper.

(a) *Service of electronic filings.* If all parties are using EOIR's electronic filing application in a specific case, the parties do not need to serve a document that is filed through EOIR's electronic filing application on the opposing party. If all parties are using EOIR's electronic filing application in a specific case, EOIR's electronic filing application will effectuate service by providing a notification of all electronically filed documents on all parties. Upon successful upload by one of the parties, EOIR will email a notification to the email addresses provided in paragraph (b) of this section. If one or more parties are not filing through EOIR's electronic filing application in a specific case, the parties must follow the service procedures in paragraph (c) of this section.

(b) *Valid email address.* Use of EOIR's electronic filing application requires a valid email address for electronic service. The immigration courts will use the email address provided through eRegistry for electronic service on participating parties. Users must immediately update their eRegistry account if their email address changes. Representatives must additionally file a new Form EOIR–28 with the immigration court if their email address changes. EOIR will consider service completed when the electronic notification is delivered to the last email address on file provided by the user.

(c) *Service of paper filings.* If electronic filing is not being used in a particular case, the party filing with the immigration court must serve a copy of the filing on the opposing party and include a certificate of service showing service on the opposing party with their filing. The immigration judge will not consider any documents or applications that do not contain a certificate of service unless service is made on the record during a hearing.

(d) *Size and format of documents.* Unless otherwise permitted by the immigration judge, all written material presented to immigration judges including offers of evidence, correspondence, briefs, memoranda, or other documents must be submitted on 8½″ x 11″ size pages, whether filed electronically or in paper. The immigration judge may require that exhibits and other written material presented be indexed, paginated, and that a table of contents be provided.

■ 12. Amend § 1003.37 by revising paragraph (a) to read as follows:

§ 1003.37 Decisions.

(a) A decision of the immigration judge may be rendered orally or in writing. If the decision is oral, it shall be stated by the immigration judge in the presence of the parties and a memorandum summarizing the oral decision shall be served on the parties. If the decision is in writing, it shall be served on the parties by personal service, mail, or electronic notification.

* * * * *

■ 13. Amend § 1003.38 by revising paragraph (b) to read as follows:

§ 1003.38 Appeals.

* * * * *

(b) The Notice of Appeal from a Decision of an Immigration Judge (Form EOIR–26) shall be filed directly with the Board of Immigration Appeals within 30 calendar days after the stating of an immigration judge's oral decision or the mailing or electronic notification of an immigration judge's written decision. If the final date for filing falls on a Saturday, Sunday, or legal holiday, this appeal time shall be extended to the next business day. A Notice of Appeal (Form EOIR–26) may not be filed by any party who has waived appeal.

* * * * *

■ 14. Amend § 1003.63 by revising the last sentence in paragraphs (f)(1) and (2), to read as follows:

§ 1003.63 Applications.

* * * * *

(f) * * *

(1) * * * A comment or recommendation not sent to the Director electronically must include proof of service on the applicant.

(2) * * * All responses must be filed with the Director and include proof of service of a copy of such response on the commenting party.

■ 15. Amend § 1003.64 by revising the last sentence in paragraph (b) to read as follows:

§ 1003.64 Approval and denial of applications.

* * * * *

(b) * * * The written notice shall be served at the address provided on the application unless the applicant subsequently provides a change of address pursuant to § 1003.66, or shall be transmitted to the applicant electronically.

* * * * *

■ 16. Amend § 1003.65 by revising the first sentence in paragraph (d)(3) to read as follows:

§ 1003.65 Removal of a provider from the List.

* * * * *

(d) * * *

(3) *Response.* The provider may submit a written answer within 30 days from the date the notice is served or is sent to the provider electronically. * * *

* * * * *

■ 17. Amend § 1003.106 by revising the second sentence in paragraph (a)(2)(ii) and the seventh sentence in paragraph (b) to read as follows:

§ 1003.106 Right to be heard and disposition.

(a) * * *

(2) * * *

(ii) * * * When designating the time and place of a hearing, the adjudicating official shall provide for the service of a notice of hearing on the practitioner or the authorized officer of the recognized organization and the counsel for the government.

* * * * *

(b) * * * The adjudicating official shall provide for service of a written decision or memorandum summarizing an oral decision on the practitioner or, in cases involving a recognized organization, on the authorized officer of the organization and on the counsel for the government. * * *

* * * * *

PART 1208—PROCEDURES FOR ASYLUM AND WITHHOLDING OF REMOVAL

■ 18. The authority citation for part 1208 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1158, 1226, 1252, 1282; Title VII of Pub. L. 110–229; Pub. L. 115–218.

■ 19. Amend § 1208.4 by revising the fifth sentence of paragraph (a)(2)(ii) to read as follows:

§ 1208.4 Filing the application.

* * * * *

(a) * * *

(2) * * *

(ii) * * * For cases before the immigration court, the application is considered to have been filed on the date it is received by the immigration court. * * *

* * * * *

PART 1214—REVIEW OF NONIMMIGRANT CLASSES

■ 20. The authority citation for part 1214 continues to read as follows:

Authority: 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; 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; 8 CFR part 2.

§ 1214.2 [Amended]

■ 21. Amend § 1214.2 (a) by:
■ a. Removing the words ''the Service'' and adding, in their place, the word ''DHS'';
■ b. Removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''; and
■ c. Removing the words ''Service custody'' and adding, in their place, the words ''DHS custody''.

PART 1240—PROCEEDINGS TO DETERMINE REMOVABILITY OF ALIENS IN THE UNITED STATES

■ 22. The authority citation for part 1240 continues to read as follows:

Authority: 8 U.S.C. 1103, 1158, 1182, 1186a, 1186b, 1225, 1226, 1227, 1228, 1229a, 1229b, 1229c, 1252 note, 1361, 1362; secs. 202 and 203, Pub. L. 105–100 (111 Stat. 2160, 2193); sec. 902, Pub. L. 105–277 (112 Stat. 2681).

§ 1240.2 [Amended]

■ 23. Amend § 1240.2 by:
■ a. Removing the words ''the Service'' and adding, in their place, the word ''DHS'';
■ b. Removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''; and
■ c. Removing the words ''Service attorney'' and adding, in their place, the words ''DHS counsel''.

§ 1240.10 [Amended]

■ 24. Amend § 1240.10 by:
■ a. Removing the words ''the Service'' and adding, in their place, the word ''DHS''; and
■ b. Removing the words ''an Service counsel'' and adding, in their place, the words ''DHS counsel''.

§ 1240.11 [Amended]

■ 25. Amend § 1240.11 by:
■ a. Removing the words ''the Service'' and adding, in their place, the word ''DHS''; and
■ b. Removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.

§ 1240.13 [Amended]

■ 26. Amend § 1240.13 by removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.

§ 1240.26 [Amended]

■ 27. Amend § 1240.26 by:
■ a. Removing the words ''the Service'' and adding, in their place, the word ''DHS''; and
■ b. Removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.

§ 1240.32 [Amended]

■ 28. Amend § 1240.32 by:
■ a. Removing the words ''the Service'' and adding, in their place, the word ''DHS''; and
■ b. Removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.

§ 1240.33 [Amended]

■ 29. Amend § 1240.33 by removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.

§ 1240.48 [Amended]

■ 30. Amend § 1240.48 by:
■ a. Removing the words ''the Service'' and adding, in their place, the word ''DHS''; and
■ b. Removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.

§ 1240.49 [Amended]

■ 31. Amend § 1240.49 by:
■ a. Removing the words ''the Service'' and adding, in their place, the word ''DHS''; and
■ b. Removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.

§ 1240.51 [Amended]

■ 32. Amend § 1240.51 by removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.
■ 33. Amend § 1240.53 by revising paragraph (a) to read as follows:

§ 1240.53 Appeals.

(a) Pursuant to 8 CFR part 1003, an appeal shall lie from a decision of an immigration judge to the Board, except that no appeal shall lie from an order of deportation entered in absentia. The procedures regarding the filing of a Form EOIR–26, Notice of Appeal, fees, and briefs are set forth in §§ 1003.3, 1003.31, and 1003.38 of this chapter. An appeal shall be filed within 30 calendar days after the mailing or electronic notification of a written decision, the stating of an oral decision, or the service of a summary decision. The filing date is defined as the date of receipt of the Notice of Appeal by the Board. The reasons for the appeal shall be stated in the Form EOIR–26, Notice of Appeal, in accordance with the provisions of § 1003.3(b) of this chapter. Failure to do so may constitute a ground for dismissal of the appeal by the Board pursuant to § 1003.1(d)(2) of this chapter.

* * * * *

PART 1245—ADJUSTMENT OF STATUS TO THAT OF PERSON ADMITTED FOR PERMANENT RESIDENCE

■ 34. The authority citation for part 1245 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1182, 1255; section 202, Pub. L. 105–100, 111 Stat. 2160, 2193; section 902, Pub. L. 105–277, 112 Stat. 2681; Title VII of Pub. L. 110–229.

■ 35. Amend § 1245.21 by:
■ a. Removing the words ''the Service'' and adding, in their place, the word ''DHS'';
■ b. Removing the words ''the Service's'' and adding, in their place, the word ''DHS's''; and
■ c. Removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.

PART 1246—RECISSION OF ADJUSTMENT OF STATUS

■ 36. The authority citation for part 1246 continues to read as follows:

Authority: 8 U.S.C. 1103, 1254, 1255, 1256, 1259; 8 CFR part 2.

§ 1246.5 [Amended]

■ 37. Amend § 1246.5 by removing the words ''Service counsel'' and adding, in their place, the words ''DHS counsel''.

PART 1292—REPRESENTATION AND APPEARANCES

■ 38. The authority citation for part 1292 continues to read as follows:

Authority: 8 U.S.C. 1103, 1362.

■ 39. Amend § 1292.1 by revising paragraphs (a)(2)(ii) through (iv), and adding paragraph (a)(2)(v) to read as follows:

§ 1292.1 Representation of others.

(a) * * *
(2) * * *
(ii) In the case of a law student, he or she has filed a statement that he or she is participating, under the direct supervision of an EOIR-registered licensed attorney or accredited representative, in a legal aid program or clinic conducted by a law school or non-profit organization, and that he or she is appearing without direct or indirect remuneration from the alien he or she represents;

(iii) In the case of a law graduate, he or she has filed a statement that he or she is appearing under the supervision of a licensed attorney or accredited representative and that he or she is appearing without direct or indirect remuneration from the alien he or she represents;

(iv) An attorney or accredited representative physically accompanies the law student or law graduate who is appearing. The accompanying attorney or accredited representative must be authorized to practice before EOIR and be prepared to proceed with the case at all times; and

(v) All filings by law students and law graduates are made through an EOIR-registered attorney or accredited representative.

* * * * *

James R. McHenry,

Director, Executive Office for Immigration Review, Department of Justice.

[FR Doc. 2020–26115 Filed 12–3–20; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 24, 25, 35, and 192

[Docket ID OCC–2020–0025]

RIN 1557–AE96

Community Reinvestment Act Regulations

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office of the Comptroller of the Currency (OCC) is issuing a notice of proposed rulemaking to request comment on the OCC's proposed approach to determine the Community Reinvestment Act (CRA) evaluation measure benchmarks, retail lending distribution test thresholds, and community development minimums under the general performance standards. The proposal further explains how the OCC would assess significant declines in CRA activities levels in connection with performance context following the initial establishment of the benchmarks, thresholds, and minimums. Finally, the proposed rule would make clarifying and technical amendments to the CRA final rule.

DATES: Comments must be received on or before February 2, 2021.

ADDRESSES: Commenters are encouraged to submit comments through the Federal eRulemaking Portal, if possible. Please use the title ''Community Reinvestment Act Regulations'' to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

• *Federal eRulemaking Portal—Regulations.gov Classic or Regulations.gov Beta*

Regulations.gov Classic: Go to *https://www.regulations.gov/.* Enter ''Docket ID OCC 2020–0025'' in the Search Box and click ''Search.'' Click on ''Comment Now'' to submit public comments. For help with submitting effective comments please click on ''View Commenter's Checklist.'' Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov,* including instructions for submitting public comments.

Regulations.gov Beta: Go to *https://beta.regulations.gov/* or click ''Visit New *Regulations.gov Site*'' from the *Regulations.gov* classic homepage. Enter ''Docket ID OCC–2020–0025'' in the Search Box and click ''Search.'' Public comments can be submitted via the ''Comment'' box below the displayed document information or click on the document title and click the ''Comment'' box on the top-left side of the screen. For help with submitting effective comments please click on ''Commenter's Checklist.'' For assistance with the *Regulations.gov* Beta site please call (877)-378–5457 (toll free) or (703) 454–9859 Monday-Friday, 9am-5pm ET or email to *regulations@erulemakinghelpdesk.com.*

• *Mail:* Chief Counsel's Office, Attention: Comment Processing, 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.

Instructions: You must include ''OCC'' as the agency name and ''Docket ID OCC–2020–0025'' in your comment. In general, the OCC will enter all comments received into the docket and publish the comments on the *Regulations.gov* website 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 rulemaking action by the following method:

• *Viewing Comments Electronically—Regulations.gov Classic or Regulations.gov Beta:*

Regulations.gov Classic: Go to *https://www.regulations.gov/.* Enter ''Docket ID OCC–2020–0025'' in the Search box and click ''Search.'' Click on ''Open Docket Folder'' on the right side of the screen. Comments and supporting materials can be viewed and filtered by clicking on ''View all documents and comments in this docket'' and then using the filtering tools on the left side of the screen. Click on the ''Help'' tab on the *Regulations.gov* home page to get information on using *Regulations.gov.* The docket may be viewed after the close of the comment period in the same manner as during the comment period.

Regulations.gov Beta: Go to *https://beta.regulations.gov/* or click ''Visit New *Regulations.gov Site*'' from the *Regulations.gov* classic homepage. Enter ''Docket ID OCC–2020–0025'' in the Search Box and click ''Search.'' Click on the ''Comments'' tab. Comments can be viewed and filtered by clicking on the ''Sort By'' drop-down on the right side of the screen or the ''Refine Results'' options on the left side of the screen. Supporting Materials can be viewed by clicking on the ''Documents'' tab and filtered by clicking on the ''Sort By'' drop-down on the right side of the screen or the ''Refine Results'' options on the left side of the screen.'' For assistance with the *Regulations.gov* Beta site please call (877)-378–5457 (toll free) or (703) 454–9859 Monday-Friday, 9am-5pm ET or email to *regulations@erulemakinghelpdesk.com.*

The docket may be viewed after the close of the comment period in the same manner as during the comment period.

FOR FURTHER INFORMATION CONTACT: Ioan Voicu, Director, Compliance Risk Analysis Division, at (202) 649–5550; or Daniel Borman, Senior Attorney, Daniel Sufranski, Attorney, or Jean Xiao, Attorney, Chief Counsel's Office, (202) 649–5490, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION:

I. Introduction

On June 5, 2020, the OCC published a final rule in the **Federal Register** (2020 final rule) to update the regulatory framework implementing the Community Reinvestment Act of 1977 (CRA) [1] for national banks and savings

[1] Community Reinvestment Act of 1977, Public Law 95–128, 91 Stat. 1147 (1977), *codified at* 12 U.S.C. 2901 *et seq.*

associations (collectively, banks).[2] The 2020 final rule was the culmination of a multi-year process of engagement with various stakeholders to ensure that the CRA remains a relevant and powerful tool for encouraging insured depository institutions to serve the needs of their entire communities, including low- and moderate-income (LMI) neighborhoods. The 2020 final rule strengthened and modernized the implementation of the CRA by making the regulatory framework more objective, transparent, consistent in application, and reflective of changes in the banking industry and how consumers bank. The OCC's goal in implementing the 2020 final rule was to make the CRA framework a better tool to encourage banks to engage in more activities to serve the needs of their communities, particularly in LMI and other historically underserved communities. These goals are consistent with the statutory purpose of the CRA to encourage insured depository institutions[3] to help meet the credit needs of the local communities in which they are chartered, including LMI neighborhoods, consistent with banks' safe and sound operations.

The 2020 final rule made changes in four areas of the historical CRA framework. Specifically, the 2020 final rule: (1) Clarified and expanded the bank lending, investment, and services that qualify for CRA consideration (collectively, qualifying activities or CRA activities); (2) updated how banks delineate the assessment areas in which they are evaluated; (3) provided additional methods for evaluating CRA performance in a consistent and objective manner; and (4) required reporting that is timely and transparent.

The new framework incentivizes banks to achieve specific performance goals. Timely and transparent CRA data, including CRA performance evaluations, will provide meaningful information to all stakeholders.

The 2020 final rule made changes to aspects of the historical CRA framework that had unintentionally inhibited banks' CRA activities by creating uncertainty about which activities would qualify and how much those activities would contribute to banks' CRA ratings. Through hearings, outreach, and public comments during the rulemaking process, the OCC learned that many banks engaged only in CRA activities for which they previously received CRA consideration and committed capital and credit only to activities for which they were confident that they would receive consideration—at the cost of innovation and responsiveness. In addition, the historical framework lacked consistent and objective evaluations and timely and transparent reporting, which inhibited the public's ability to understand how and to what extent banks were meeting community credit needs.

By moving to a system that is primarily objective and transparent under the 2020 final rule, CRA ratings will be more consistent, reproducible, and comparable over time. The agency's 2020 final rule was designed so that similar circumstances will be evaluated in a similar manner from bank to bank.

In the 2020 final rule, the OCC finalized the framework for the general performance standards (*i.e.,* the CRA evaluation measure, retail lending distribution tests, community development (CD) minimums, and the percentage of assessment areas for which a bank must receive a satisfactory or outstanding assigned rating to achieve a bank presumptive rating of satisfactory or outstanding); however, the OCC decided not to adopt the specific CRA evaluation measure benchmarks, retail lending distribution test thresholds, and CD minimums as initially proposed. As noted in the preamble of the 2020 final rule, the OCC believes that it is appropriate to gather more information and further calibrate these measures, and the agency stated that it would issue a proposal that would explain the process the OCC will use to more precisely calibrate the benchmark, threshold, and minimum values.[4]

This proposal seeks comment on the approach the OCC would use to set these benchmarks, thresholds, and minimums. As described further in this **SUPPLEMENTARY INFORMATION** section, the OCC is separately seeking data through an Information Collection Survey from banks subject to the general performance standards.[5] Once the OCC analyzes the public comments on this proposal and the data it receives, the OCC plans to issue a final rule that will adopt an approach for setting the benchmark, threshold, and minimum values that correspond to the presumptive ratings[6] (*i.e.,* outstanding, satisfactory, needs to improve, and substantial noncompliance) for banks assessed under the general performance standards. In addition, once the OCC has determined the specific benchmarks, thresholds, and minimums according to the selected approach, the agency will take the appropriate steps to publicize the standards and engage stakeholders regarding the specific benchmarks, thresholds, and minimums. Once finalized, the OCC expects to periodically review and adjust these benchmarks, thresholds, and minimums, as necessary, to ensure that these measures are incentivizing banks to engage in appropriate levels of CRA activities, while taking into consideration market conditions and changes in economic cycles. The OCC also expects to take the appropriate steps to publicize the future adjustments to the benchmarks, thresholds, and minimums and engage stakeholders on these adjustments.

II. Background

The OCC's 2020 final rule incorporates many of the measures and methods the OCC historically has used to assess CRA performance, but it also provides clarity about how the OCC will use those mechanisms to assess a bank's CRA performance. Among other things, the 2020 final rule describes what activities will qualify for CRA credit and how they will be measured to assess CRA performance. Further, the 2020 final rule explains that banks are expected to meet specific benchmarks, thresholds, and minimums in order to achieve presumptive CRA ratings.

[2] 85 FR 34734 (June 5, 2020). As used throughout this notice, the term ''bank'' or ''banks'' also includes uninsured Federal branches that result from an acquisition described in section 5(a)(8) of the International Banking Act of 1978 (12 U.S.C. 3103(a)(8)). The rulemaking authority of the Office of Thrift Supervision (OTS) and the Director of the OTS, respectively, relating to savings associations was transferred to the OCC in Title III of the Dodd–Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376, 1522 (2010). As a result, the OCC has CRA rulewriting authority for both Federal and state savings associations, as well as for national banks. The OCC also has rulewriting authority for Federal and state savings associations for purposes of the CRA specifically pursuant to 12 U.S.C. 2905.

[3] 12 U.S.C. 1813(c)(2).

[4] 85 FR at 34774.

[5] Twelve CFR 25.10(a) of the 2020 final rule applies the general performance standards to banks with more than $2.5 billion in assets that are not evaluated under a strategic plan and that are not wholesale or limited purpose banks. Under § 25.10(b) of the 2020 final rule, small, intermediate, wholesale, and limited purpose banks can opt into and elect to be evaluated under the general performance standards. For purposes of the Information Collection Survey, the OCC is not collecting data from any small, intermediate, wholesale, and limited purpose banks.

[6] Under § 25.13 of the 2020 final rule, banks assessed under the general performance standards receive presumptive ratings at both the bank and assessment area level based on their performance on objective criteria (*i.e.,* the CRA evaluation measure, retail lending distribution test performance, CD minimum calculation, and the percentage of assessment areas in which the bank received a satisfactory or outstanding assigned rating). Those presumptive ratings are adjusted for performance context and evidence of discriminatory or other illegal credit practices to determine the assigned rating pursuant to § 25.19 of the 2020 final rule.

Under the 2020 final rule, banks assessed under the general performance standards will be evaluated based on (1) the distribution of their retail loans (*i.e.,* home mortgage loans, small loans to businesses, small loans to farms, and consumer loans) (retail lending distribution tests); (2) the dollar value of qualifying retail loans and CD activities and the distribution of their branches in each assessment area and at the bank level (CRA evaluation measure); and (3) the level of their CD activities in each assessment area and at the bank level (CD minimum calculation).

Twelve CFR 25.13 of the 2020 final rule provides the general performance standards and describes how they are applied to determine bank and assessment area presumptive ratings. Section 25.13(d) of the 2020 final rule states that a bank's presumptive assessment area rating is based on its CRA evaluation measure, CD minimum calculation, and performance on the retail lending distribution tests. Section 25.13(c) of the 2020 final rule states that the bank-level presumptive rating is based on the CRA evaluation measure, CD minimum calculation, and assigned ratings in its assessment areas. Sections 25.11 and 25.13 of the 2020 final rule require a bank to determine its CRA evaluation measure and CD minimum calculation in each assessment area and at the bank level. As described in § 25.11 of the 2020 final rule, the CRA evaluation measure is the sum of the bank's annual qualifying activities values (including any applicable multipliers [7]) *divided* by its annual average quarterly retail domestic deposits value plus the percentage of the bank's branches in certain areas of need multiplied by .02, subject to a cap on the value of branches of one percentage point. The bank's average annual CRA evaluation measure at both the assessment area level and at the bank level will be compared to a specific quantitative benchmark, which is to be determined by the OCC.

Under § 25.13 of the 2020 final rule, the CD minimum calculation is determined by *dividing* the total quantified dollar value of a bank's CD loans and CD investments, including any applicable multipliers, by the bank's average quarterly retail domestic deposits value. The bank's CD minimum calculations at both the assessment area level and at the bank level will be compared to the CD minimums to be determined by the OCC.

Section 25.12 of the 2020 final rule describes the application of the retail lending distribution tests. The retail lending distribution tests evaluate the geographic and borrower distributions of a bank's major retail lending product lines in assessment areas in which the bank has originated 20 or more loans in those product lines per year during an evaluation period. The geographic distribution test evaluates the percentage of a bank's retail loan originations in LMI census tracts, and the borrower distribution test evaluates the percentage of a bank's retail loan originations to LMI borrowers, CRA-eligible businesses, and CRA-eligible farms, as applicable. Section 25.13 of the 2020 final rule requires a bank to pass both the geographic and borrower distribution tests for each applicable product line to receive a presumptive rating of satisfactory or outstanding in an assessment area. Section 25.12 of the 2020 final rule allows a bank to pass each test based on its performance relative to either the demographic comparator, which is based on the demographics of a given assessment area, or the peer comparator, which is based on peer performance in a given assessment area. The OCC will determine the thresholds to pass the borrower distribution test and geographic distribution test for both the demographic and peer comparators.

Although performance on the retail lending distribution tests is only evaluated at the assessment area level, § 25.13 of the 2020 final rule provides that in order to achieve a satisfactory or outstanding presumptive rating at the bank level, a bank with more than five assessment areas must receive an assigned rating of at least satisfactory or outstanding, respectively, in: (1) 80 percent of its assessment areas; and (2) assessment areas from which the banks receives 80 percent of its retail domestic deposits that it receives from its assessment areas. For a bank with five or fewer assessment areas to achieve a satisfactory or outstanding presumptive rating at the bank level, the bank must receive an assigned rating of at least satisfactory or outstanding, respectively, in: (1) 50 percent of its assessment areas; and (2) assessment areas from which the bank receives 80 percent of its retail domestic deposits that it receives from its assessment areas. Banks that do not meet these standards or the bank-level CD minimum requirement will receive a presumptive rating of needs to improve or substantial noncompliance, depending on the bank-level CRA evaluation measure.

In the preamble to the 2020 final rule, the OCC indicated that it would set the objective CRA evaluation measure benchmarks, retail lending distribution test thresholds, and CD minimums for the level of performance necessary to achieve each presumptive rating category at a later date, and that it would apply these benchmarks, thresholds, and minimums as of January 1, 2023, which is the compliance date applicable to banks subject to the general performance standards.[8] This proposal suggests an approach to determine those objective benchmarks, thresholds, and minimums.

III. Information Collection Survey

Separate from this proposal, the OCC will issue an Information Collection Survey to obtain bank-specific information from banks subject to the general performance standards, which will assist the OCC in determining the CRA evaluation measure benchmarks, retail lending distribution test thresholds, and CD minimums under the 2020 final rule that will correspond to the presumptive ratings. This information collection will supplement existing OCC data and facilitate a broader review of the framework going forward, which may inform additional revisions in future years.

[7] The purpose of multipliers is to incentivize banks to engage in activities that are particularly valuable and important from a CRA perspective by giving banks additional credit towards their CRA evaluation measures and CD minimum calculations for these activities. Under § 25.08 of the 2020 final rule, banks may be eligible for multipliers for the following: (1) Activities provided to or that support minority depository institutions, women's depository institutions, Community Development Financial Institutions, and low-income credit unions, except activities related to mortgage-backed securities; (2) other CD investments, except CD investments in mortgage-backed securities and municipal bonds; (3) other CD services; (4) other affordable housing-related CD loans; (5) retail loans generated by branches in LMI census tracts; and (6) qualifying activities in CRA deserts. Pursuant to § 25.08(b)(4) of the 2020 final rule, qualifying activities that receive a multiplier may be eligible for an additional multiplier based on the OCC's determination of the activity's responsiveness, innovativeness, or complexity. Further, to ensure that the use of multipliers does not reduce the level of CD activities that banks conduct, a bank is not eligible for multipliers until the quantified dollar values of its current period CD activities are approximately equal to the quantified dollar values of CD activities in its prior evaluation period. As described below, this proposal would make clarifying edits to the multiplier for activities that are determined to be particularly responsive, innovative, or complex. Additionally, as discussed below, this proposal would clarify that to be eligible for the multipliers described in § 25.08, the quantified dollar value of a bank's current evaluation period CD loans, CD investments, and CD services must be ''approximately equal to or greater than'' the quantified dollar value of these activities considered in the bank's prior evaluation period.

[8] 85 FR at 34736. The OCC would also apply these benchmarks, thresholds, and minimums for banks that opt into the general performance standards at the time of opt in.

Specifically, the OCC will request four types of bank data or information. First, the OCC will collect data on banks' main office presence, branch presence, deposit-taking facility presence, retail domestic deposit data at the county level, and what banks' facility-based and deposit-based assessment areas would have been under the standards in § 25.09. This data will assist the OCC in determining how banks would have performed under the general performance standards and the banks' presumptive ratings under §§ 25.10 through 25.13 of the 2020 final rule. Second, the OCC will collect data on what would have been the quantified dollar value of banks' CRA qualifying activities under the 2020 final rule to determine what banks' performance would have been on the CRA evaluation measure under § 25.11 of the 2020 final rule and the CD minimum under § 25.13(c) and (d) of the 2020 final rule. Third, the OCC will collect data on retail loan applications and on what would have been the quantified dollar value of banks' CRA qualifying retail loan originations to determine the CRA evaluation measure under § 25.11 of the 2020 final rule. Obtaining information on retail loan applications and originations will, in the near term, help inform the OCC about banks' credit supply decisions across geographies and, over time, assist the OCC in refining and improving the CRA framework.[9] Finally, the OCC will collect information on banks' branch locations to determine what would have been the branch distribution component of the CRA evaluation measure under § 25.11 of the 2020 final rule.

IV. Description of Proposed Rule

A. Proposed Approach for Setting the Benchmarks, Thresholds, and Minimums

The OCC is seeking to set CRA evaluation measure benchmarks, retail lending distribution test thresholds, and CD minimums that provide objectivity and transparency for banks evaluated under the general performance standards, while also encouraging banks to engage in CRA activities at a level no less than the status quo.[10] To accomplish these goals, the OCC is proposing to establish benchmarks, thresholds, and minimums that correspond to a proportion of banks that would have received a hypothetical bank-level presumptive CRA rating of outstanding and satisfactory that is no greater than the historical proportion of banks that have received a bank-level assigned CRA rating of outstanding and satisfactory.[11]

Using banks' responses to the information collection, the OCC would calculate CRA evaluation measures and CD minimum calculations for each bank's assessment areas, as well as a bank-level CRA evaluation measure and CD minimum calculation for each bank. Similarly, for each major retail lending product line, the OCC would calculate the numerator used in determining each bank's retail lending distribution test ratios for each bank's assessment areas. After combining data from the Census and Dun and Bradstreet files of businesses, the OCC would then calculate the demographic comparator under the borrower and geographic distribution tests for each retail lending product line, if applicable, for every bank's assessment areas. Similarly, the OCC would use data collected from all banks subject to the general performance standards to calculate the peer comparator under the borrower and geographic distribution tests for each retail lending product line, if applicable, for every bank's assessment areas. Each bank's numerators under the borrower and geographic distribution tests would be divided by the applicable demographic and peer comparators to calculate each bank's retail lending distribution test ratios for each bank's assessment areas. These calculations would result in (1) bank-level distributions of the CRA evaluation measure and CD minimum calculation and (2) assessment area-level distributions of the CRA evaluation measure, CD minimum calculation, and the borrower and geographic distribution test ratios.

Using the dataset described above, possibly combined with other datasets, the OCC would examine possible combinations of benchmark, threshold, and minimum values. For each set of benchmarks, thresholds, and minimums, the OCC would iteratively calculate the proportion of assessment areas that would pass for each bank. Subsequently, the OCC would determine the proportion of banks that would meet or exceed the bank-level CD minimum and the bank-level CRA evaluation measure benchmark. The OCC would compare the results to the historical proportion of outstanding ratings under the prior CRA framework to ensure that the chosen set of benchmarks, thresholds, and minimums yields a proportion of outstanding ratings that is no greater than the historical proportion. The OCC would determine the appropriate set of benchmarks, thresholds, and minimums for a satisfactory rating using the same approach. In the OCC's analysis, the banks that do not meet or exceed the benchmarks, thresholds, or minimums for satisfactory and outstanding ratings would receive a needs to improve or substantial noncompliance rating, depending on the criteria outlined in the 2020 final rule.

If the OCC identifies multiple combinations of benchmarks, thresholds, and minimums that result in a similar proportion of banks that pass, the OCC would consider additional criteria, such as incentives to further increase CRA activities that benefit LMI individuals and distressed or underserved areas, to identify the most appropriate set of performance standard values.

To maintain flexibility, the OCC would not require any of the benchmark, threshold, or minimum values to be similar to each other. That is, the information collection may reveal that distributions of the various CRA performance standards differ across retail lending product lines and aggregation levels. For example, the distribution of the mortgage product line may be significantly different from that of the automobile loan or small loan to a business product lines. Similarly, the distribution of the CRA evaluation measure at the assessment area level may differ from that at the bank level. As such, the OCC anticipates that there may be as many as 26 different calibrated benchmark, threshold, and minimum values under the general performance standards. Specifically, the retail lending distribution tests reflect six retail lending product lines for the borrower distribution test, three retail lending product lines for the geographic distribution test, and involve two different comparisons under each test,

[9] See various studies using application information to understand credit supply such as: Antoniades, A. 2016. ''Liquidity Risk and the Credit Crunch of 2007–2008: Evidence from Micro-Level Data on Mortgage Loan Applications.'' *Journal of Financial and Quantitative Analysis* 51(6): 1795–1822; Mian, Atif, and Amir Sufi. 2009. ''The Consequences of Mortgage Credit Expansion: Evidence from the U.S. Mortgage Default Crisis.'' *The Quarterly Journal of Economics* 124(4): 1449–1496; Puri, Manju, Jorg Rocholl, and Sascha Steffen. 2011. ''Global Retail Lending in the Aftermath of the US Financial Crisis: Distinguishing Between Supply and Demand Effects.'' *Journal of Financial Economics* 100(3): 556–578.

[10] Stakeholders can make only educated guesses about the current level of bank CRA activities because there is no standardized set of data or information about the actual levels of bank CRA activities. The Information Collection Survey will assist the OCC in making a more informed estimate of the current level of bank CRA activities.

[11] The population of banks being analyzed under this approach is the same population of banks subject to the Information Collection Survey (*i.e.,* banks with assets of $2.5 billion or more that are subject to the general performance standards under the 2020 final rule).

thus yielding up to 18 different threshold values. The CRA evaluation measure would involve six different benchmark values (one at the bank level and one at the assessment area level for needs to improve, satisfactory, and outstanding presumptive ratings, respectively), while the CD minimum would involve two values, one at the bank level and one at the assessment area level.

B. Alternatives Considered to the Proposed Approach for Setting the Benchmarks, Thresholds, and Minimums

The OCC recognizes that some extent of normative judgment is necessary for any approach the OCC chooses. The OCC considered proposing an alternative where instead of the proposed approach, the OCC would choose a set of benchmarks, thresholds, and minimums without reference to the historical distribution of ratings. The OCC chose not to propose this approach because the OCC believes that setting benchmarks, thresholds, and minimums in relation to the historic status quo minimizes the degree of normative judgment and provides a useful starting point for determining an expected distribution of CRA ratings.

The OCC also considered proposing using the information collection to calculate the historical aggregate distribution and dollar amount of CRA activities for the components of the general performance standards to set benchmarks, thresholds, and minimums. This approach would consider the CRA activities, branches, and retail domestic deposits of all banks as if they were the CRA activities, branches, and retail domestic deposits of a single hypothetical bank in order to set the thresholds, benchmarks, and minimums that correspond to the desirable level of CRA activity.

The OCC chose not to propose this approach because of the additional assumptions and constraints it would entail. First, the OCC views this approach as unworkable for the retail lending distribution tests. Consolidating all banks would prevent the calculation of the peer comparator because the hypothetical, aggregate bank has no peers. For the demographic comparator, this approach would require either using nationwide demographics (*i.e.,* the proportion of LMI families, LMI tracts, or owner-occupied units in LMI tracts in the entire United States) or assuming how the hypothetical aggregate bank would delineate its assessment areas. Because each bank's lending activities likely do not cover all areas in which LMI families reside or all the LMI tracts nationwide, and individual banks delineate their own assessment areas pursuant to § 25.09 of the 2020 final rule, it is unclear whether this approach would be appropriate. Second, without further data analysis, the approach may be disproportionately influenced by the activities of the largest banks assessed under the general performance standards, which are responsible for the majority of CRA activities and deposits. Lastly, the OCC does not believe that this approach would sufficiently capture the interaction between the benchmarks, thresholds, and minimums, making it difficult to predict a resulting distribution of presumptive ratings for a set of chosen values.

Having considered different approaches to setting the benchmarks, thresholds, and minimums, the OCC is proposing an approach that would set robust benchmarks, thresholds, and minimums. The OCC believes that the proposed approach will effectively achieve the agency's goals of providing objectivity and transparency in the performance standards, while also encouraging banks to engage in CRA activities at an aggregate level that is no less than the status quo.

C. Proposed Approach for Treating Declines in CRA Performance Following the Initial Establishment of the Benchmarks, Thresholds, and Minimums

The OCC is proposing to amend § 25.16 of the 2020 final rule to state that banks whose performance precipitously decreases by ten percent [12] or more on the general performance standards after the establishment of the initial benchmarks, thresholds, and minimums without an adequate explanation under the performance context criteria, including consideration of market conditions, risk having their assigned ratings adversely impacted.

The OCC recognizes that for any well-defined set of benchmarks, thresholds, minimums, and CRA presumptive ratings, the current CRA activities of some banks will fall below, while the current CRA activities of other banks will exceed, the chosen set of benchmarks, thresholds, and minimums. The former set of banks would be expected to increase CRA activities, whereas the latter set of banks could potentially decrease CRA activities while maintaining the same rating or achieving a better rating under the new benchmarks, thresholds, and minimums. This potential decrease in CRA activities by some banks may negate any increase in CRA activities that would result from other banks increasing their CRA activities to meet the new benchmarks, thresholds, and minimums. Therefore, with the proposed approach and alternative approaches considered, the OCC recognizes the need to evaluate precipitous declines in CRA activity under performance context as banks adapt to the new benchmarks, thresholds, and minimums.

As a general matter, it is appropriate for banks to adjust their CRA activities over time in response to regulatory requirements. This is normal and acceptable. That said, precipitous declines of ten percent or more in a bank's performance on the general performance standards as calculated based on historical data, between the establishment of the objective benchmarks, thresholds, and minimums and the bank's first evaluation under the general performance standards, that cannot be explained by market conditions or other performance context criteria may result in the bank receiving an assigned rating that is no higher than needs to improve at the assessment area level as well as at the overall bank level.

V. 2020 Final Rule Clarifying and Technical Amendments

Following publication of the 2020 final rule, the OCC engaged in a review process with the goal of providing additional clarity to 12 CFR part 25, effective October 1, 2020. The OCC seeks comment on revisions to aspects of the 2020 final rule, including compliance dates, some definitions, multipliers, the general performance standards opt out, the aggregate disclosure statement, and references to the FDIC. In addition, the proposal contains various technical, clarifying, and conforming amendments.

A. Compliance Dates for Banks Evaluated Under a Strategic Plan

Under the 2020 final rule, all banks have the option to be evaluated under a strategic plan, including banks that meet the small or intermediate bank definitions. The 2020 final rule also sets forth compliance dates for certain sections of the rule based on bank type. Section 25.01(c)(4)(i) of the 2020 final rule states that ''[b]anks other than small, intermediate, wholesale, and limited purpose banks must comply with §§ 25.07—25.13, 25.21, 25.25, and 25.26 by January 1, 2023.'' This provision was intended to apply to banks evaluated under a strategic plan,

[12] This proposed ten percent figure is based on the expert judgment of the OCC Economics Department and is a reasonable representation of what the OCC currently considers to be a precipitous decrease in a bank's CRA activities.

and the sections referenced in this paragraph are applicable to banks evaluated under a strategic plan or the general performance standards (*e.g.,* § 25.21 includes the data collection requirements for banks evaluated under the general performance standards or a strategic plan). In contrast, § 25.01(c)(4)(iii) of the 2020 final rule includes the compliance dates applicable to small and intermediate banks. To eliminate any potential confusion regarding which compliance dates apply to banks evaluated under a strategic plan that also meet either the small bank or intermediate bank definition, the proposal would revise § 25.01(c)(4)(i) to clarify that banks other than those evaluated under the performance standards applicable to small, intermediate, wholesale, and limited purpose banks must comply with the applicable sections by January 1, 2023.

B. Definitions

In § 25.03 of the 2020 final rule, the definition of ''compensation'' refers to ''median hourly compensation value (*i.e.,* total salaries and benefits divided by full-time equivalent employees).'' It also describes the calculation as being based on aggregate Call Report data on median salaries and benefits and the median number of full-time equivalent employees. The OCC determined that the two descriptions are inconsistent and may result in different compensation levels. The OCC intended for the definition of ''compensation'' to reflect the median hourly compensation value based on each bank's total salaries and benefits and its full-time equivalent employees. Therefore, the proposed rule would revise the definition of ''compensation'' to clarify this approach for determining compensation value. Under the 2020 final rule's definitions of ''partially'' and ''primarily,'' it is possible that an activity could meet both definitions if the activity has an express, bona fide intent, purpose, or mandate, consistent with a criterion in § 25.04(c) of the 2020 final rule. To eliminate the potential overlap in the definitions, the proposal would revise the definition of ''partially'' to clarify that the definition applies to activities that do not have an express, bona fide intent, purpose, or mandate consistent with a criterion in § 25.04(c) of the 2020 final rule. The proposal also would revise the definitions of ''partially'' and ''primarily'' to clarify that the terms apply to activities involving ''families, businesses, or farms'' to ensure consistency with the qualifying activities criteria that use those terms.

C. Multiplier Clarifications

Section 25.08(b) of the 2020 final rule includes multipliers for some qualifying activities, including a multiplier for activities that are determined to be particularly responsive, innovative, or complex. The proposal would clarify that this multiplier is applicable to any activity that received one of the other multipliers provided for in the 2020 final rule and that the maximum total upward adjustment considering all multipliers is four times the quantified dollar value of the qualifying activity. Section 25.08(b)(1) also provides that to be eligible for the multipliers in sections 25.08(b)(2) and (b)(3) of the 2020 final rule, the quantified dollar value of a bank's current evaluation period CD loans, CD investments, and CD services must be ''approximately equal to'' the quantified dollar value of these activities considered in the bank's prior evaluation period. The proposal would clarify that the quantified dollar value of a bank's current evaluation period CD loans, CD investments, and CD services must be ''approximately equal to or greater than'' the quantified dollar value of these activities considered in the bank's prior evaluation period.

D. General Performance Standards Opt Out

Section 25.10(b) of the 2020 final rule permits a small, intermediate, wholesale, or limited purpose bank that opted into the general performance standards a single opportunity to opt out of evaluation under those standards. The 2020 final rule stated that banks that elected to opt out of evaluation under the general performance standards would ''revert'' to being evaluated according to the small and intermediate performance standards or the wholesale and limited purpose performance standards. This provision may lead to confusion in circumstances where a bank meets a different bank size or type definition when it opts into the general performance standards than it does when it elects to opt out. The proposal would revise the opt out provision to clarify that banks are subject to the applicable performance standards based on the bank's size or type when it opts out.

E. References to the Federal Deposit Insurance Corporation (FDIC)

The 2020 final rule integrates 12 CFR part 195 into 12 CFR part 25 and eliminates the former part 195. As of October 1, 2020, national banks and Federal savings associations supervised by the OCC and state savings associations supervised by the FDIC will be evaluated under part 25. The proposal would add references to the FDIC where they were inadvertently omitted in the 2020 final rule.

F. Aggregate CRA Disclosure Statement

Section 25.27(b) of the 2020 final rule provides for public disclosure of the retail loan origination data reported to the OCC that is necessary to evaluate banks' performance under the retail lending distribution tests. The OCC intended to include all data reported to the OCC regarding retail loan originations in the aggregate disclosure statement but inadvertently omitted disclosure of banks' number of home mortgage loans in LMI census tracts. The proposal would add this disclosure requirement to the rule.

G. Other Revisions

In addition to the revisions discussed above, the proposal would make several non-substantive technical, clarifying, and conforming revisions throughout the 2020 final rule to improve clarity and consistency. The OCC is also proposing revisions to regulations that include cross references to the CRA implementing regulations in effect prior to October 1, 2020, including 12 CFR part 24, 12 CFR part 35, and 12 CFR part 192. These revisions update the cross references to be consistent with the 2020 final rule and include transition provisions as appropriate.

VI. Request for Comments

The OCC requests comment on all aspects of the proposed rule. The OCC specifically requests comments on the approach the OCC would use to determine the CRA evaluation measure benchmarks, retail lending distribution test thresholds, and CD minimums under the Community Reinvestment Act's general performance standards. The OCC also seeks comment on its proposal to amend the 2020 final rule to consider, under performance context, declines of ten percent or greater on a bank's performance under the general performance standards following the establishment of the benchmarks, thresholds, and minimums.

VII. Regulatory Analyses

A. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC has reviewed the notice of proposed rulemaking and

determined that it would not introduce any new or revise any existing collection of information pursuant to the PRA. Therefore, no submission will be made to OMB for review.

B. Regulatory Flexibility Act

In general, the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires an agency, in connection with a proposed rule, to prepare an Initial Regulatory Flexibility Analysis describing the impact of the rule on small entities (defined by the Small Business Administration for purposes of the RFA to include commercial banks and savings institutions with total assets of $600 million or less and trust companies with total assets of $41.5 million of less). However, under section 605(b) of the RFA, this analysis is not required if an agency certifies that the rule would not have a significant economic impact on a substantial number of small entities and publishes its certification and a short explanatory statement in the **Federal Register** along with its rule.

The OCC currently supervises approximately 1,067 insured depository institutions, of which 1,030 may be impacted by the proposed rule. Moreover, 745 of the institutions are small entities.[13] The OCC estimates that the proposed rule's technical amendments and updated cross references may impact approximately 708 of these small entities, which is a significant number.[14] However, because the OCC estimates the costs, if any, associated with the proposal would be *de minimis,* the proposed rule would not have a significant economic impact on any small OCC-regulated entities. Additionally, the other sections of the proposed rule do not impose new mandates and primarily request comment on the OCC's proposed approach for setting the benchmarks, thresholds, and minimums as well as how the OCC would consider decreases in CRA activities following the establishment of these standards.[15] Therefore, the OCC believes the costs associated with the proposal, if any, would be *de minimis.* For these reasons, the OCC certifies that, if adopted, the proposed rule would not have a significant economic impact on a substantial number of small entities regulated by the OCC. Accordingly, an Initial Regulatory Flexibility Analysis is not required.

C. Unfunded Mandates Reform Act of 1995

The OCC has analyzed the proposed rule under the factors in the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.* Under this analysis the OCC considered whether the proposed rule includes a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year ($157 million as adjusted annually for inflation). The UMRA does not apply to regulations that incorporate requirements specifically set forth in law.

As discussed above, the proposed rule, if implemented, would not impose new mandates. The OCC concludes that if implemented, the proposed rule would not result in an expenditure of $157 million or more annually by State, local, and tribal governments, or by the private sector. Therefore, the OCC finds that the proposed rule does not trigger the UMRA cost threshold. Accordingly, the OCC has not prepared the written statement described in section 202 of the UMRA.

D. Riegle Community Development and Regulatory Improvement Act of 1994

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA), 12 U.S.C. 4802(a), in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, the OCC will consider, consistent with principles of safety and soundness and the public interest: (1) Any administrative burdens that the proposed rule would place on depository institutions, including small depository institutions and customers of depository institutions; and (2) the benefits of the proposed rule. The OCC requests comment on any administrative burdens that the proposed rule would place on depository institutions, including small depository institutions, and their customers, and the benefits of the proposed rule that the OCC should consider in determining the effective date and any administrative compliance requirements for a final rule.

List of Subjects

12 CFR Part 24

Community development, Credit, Investments, Low- and moderate-income housing, National banks, Reporting and recordkeeping requirements, Rural areas, Small businesses.

12 CFR Part 25

Community development, Credit, Investments, National banks, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 35

Community development, Credit, Freedom of information, Investments, National banks, Reporting and recordkeeping requirements.

12 CFR Part 192

Reporting and recordkeeping requirements, Savings associations, Securities.

For the reasons set out in the preamble, the OCC proposes to amend 12 CFR chapter I as follows:

PART 24—COMMUNITY AND ECONOMIC DEVELOPMENT ENTITIES, COMMUNITY DEVELOPMENT PROJECTS, AND OTHER PUBLIC WELFARE INVESTMENTS

■ 1. The authority citation for part 24 continues to read as follows:

Authority: 12 U.S.C. 24(Eleventh), 93a, 481 and 1818.

§ 24.2 [Amended]

■ 2. In § 24.2 amend paragraph (f) by removing ''12 CFR 25.12(m)'' and adding in its place ''12 CFR 25.03''.

§ 24.3 [Amended]

■ 3. Section 24.3 is amended by removing the phrase ''12 CFR 25.23 as a ''qualified investment.'''' and adding in its place the phrase ''12 CFR 25.04 as a ''community development investment.'''''.

§ 24.7 [Amended]

■ 4. In § 24.7 amend (paragraph (b) by removing ''12 CFR 25.23'' and adding in its place ''12 CFR 25.04''.

[13] Consistent with the General Principles of Affiliation 13 CFR 121.103(a), the OCC counts the assets of affiliated financial institutions when determining if it should classify an institution as a small entity. The OCC used December 31, 2019, to determine size because a ''financial institution's assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.'' *See* footnote 8 of the U.S. Small Business Administration's *Table of Size Standards.*

[14] The OCC excluded entities with a CRA examination type of ''exempt'' in an OCC supervisory information system.

[15] As noted above, these sections of the proposal are relevant to banks subject to the general performance standards, which generally only apply to institutions that have more than $2.5 billion in assets that are not evaluated under a strategic plan and that are not wholesale or limited purpose banks.

PART 25—COMMUNITY REINVESTMENT ACT AND INTERSTATE DEPOSIT PRODUCTION REGULATIONS

■ 5. The authority citation for part 25 continues to read as follows:

Authority: 12 U.S.C. 21, 22, 26, 27, 30, 36, 93a, 161, 215, 215a, 481, 1462a, 1463, 1464, 1814, 1816, 1828(c), 1835a, 2901 through 2908, 3101 through 3111, and 5412(b)(2)(B).

■ 6. Section 25.01 amended by:
■ a. In paragraph (b)(1) adding the phrase ''or the Federal Deposit Insurance Corporation (FDIC)'' after ''(OCC)'';
■ b. In paragraph (b)(2) adding the phrase ''or FDIC'' after ''OCC'';
■ c. In paragraph (c)(1) removing ''§ 25.03'' and adding ''§ 25.03,'' in its place;
■ d. Revising paragraph (c)(4)(i); and
■ e. In paragraph (c)(5):
■ i. Removing ''October 1, 2020.'' and adding ''October 1, 2020,'' in its place;
■ ii. Adding the phrase ''or FDIC'' after ''OCC'' in the introductory text; and
■ iii. Removing the word ''element'' and adding in its place the word ''elements'' in the introductory text.

The revision reads as follows:

§ 25.01 Authority, purposes, scope, and severability.

* * * * *

(c)* * *

(4) *Compliance dates.* (i) Banks other than banks evaluated under the performance standards applicable to small, intermediate, wholesale, and limited purpose banks must comply with §§ 25.07–25.13, 25.21, 25.25, and 25.26, as applicable, by January 1, 2023.

* * * * *

§ 25.02 [Amended]

■ 7. Section 25.02 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a) introductory text;
■ b. Adding the phrase ''or FDIC'' after ''OCC'' in the second sentence of paragraph (b); and
■ c. In paragraph (c):
■ i. Adding the phrase ''or FDIC'' after ''OCC''; and
■ ii. Removing the phrase ''OCC's procedures set forth in part 5 of this chapter'' and adding in its place the phrase ''applicable comment procedures''.

■ 8. Section 25.03 is amended by:
■ a. In the definition of *Affiliate* removing the phrase ''October 1, 2020'' and adding the phrase ''October 1, 2020,'' in its place;
■ b. In the definition of *Automated teller machine (ATM)* removing the phrase ''cash dispersed'' and adding the phrase ''cash is disbursed'' in its place;
■ c. Revising the definition of *Compensation;*
■ d. In the definition of *Essential community facility* removing the word ''*means*'' and adding the word ''means'' in its place*;*
■ e. In the definition of *Essential infrastructure:*
■ i. Removing the word ''*means*'' and adding the word ''means'' in its place; and
■ ii. Adding the word ''and'' before the word ''tunnels'' in paragraph (1);
■ f. Moving the definition of *Low-income credit union* to follow the definition of *Limited purpose bank;*
■ g. In the definition of *Metropolitan division* adding the word ''the'' before the phrase ''successor publication thereof'';
■ h. In the definition of *Metropolitan statistical area* adding the word ''the'' before the phrase ''successor publication thereof'';
■ i. Revising the definition of *Partially;*
■ j. In the definition of *Primarily* removing the phrase ''individuals or census tracts'' from paragraph (1) and adding in its place the phrase ''individuals, families, businesses, farms, or census tracts'';
■ k. In the definition of *Retail domestic deposit:*
■ i. Removing ''FDIA'' in the introductory text and adding in its place the phrase ''Federal Deposit Insurance Act'' in the first sentence of the definition;
■ ii. Removing ''FDIA'' and adding in its place ''Federal Deposit Insurance Act'' in paragraph (2)(i)(A); and
■ iii. Adding quotation marks to the phrase ''reciprocal deposit'' in paragraph (2)(ii);
■ l. In the definition of *Metropolitan division* removing the phrase ''the center of the census tract if the census tract'' in paragraph (2)(i)(D) and adding in its place the word ''the center of the census tract if it''; and
■ m. In the definition of *Wholesale bank* adding the word ''loans'' after the word ''mortgage''.

The revisions read as follows:

§ 25.03 Definitions.

* * * * *

Compensation means the median hourly compensation value (where compensation value equals total salaries and benefits divided by full-time equivalent employees) for the banking industry based on Call Report data for—

(1) Salaries and employee benefits from Schedule RI, Item 7.a; and

(2) Number of full-time equivalent employees from Schedule RI, Memorandum Item 5.

* * * * *

Partially means 50 percent or less of the dollar value of the activity or of the individuals, families, businesses, farms, or census tracts served by the activity, if the activity does not have an express, bona fide intent, purpose, or mandate consistent with a criterion in § 25.04(c).

* * * * *

§ 25.04 [Amended]

■ 9. In § 25.04 amend paragraph (a)(3) by removing the phrase ''on the date'' and adding in its place the word ''conducted'';

§ 25.06 [Amended]

■ 10. In § 25.06 amend paragraph (c)(2) by removing the word ''activity'' and adding in its place the word ''area''.

■ 11. Section 25.08 is amended by:
■ a. Adding the phrase ''or greater than'' after the phrase ''approximately equal to'' in the first sentence of paragraph (b)(1);
■ b. Removing the word ''conducted'' in the second sentence of paragraph (b)(1) and adding ''conducted,'';
■ c. Removing the word ''activity'' and adding in its place the word ''activities'' in paragraph (b)(2); and
■ d. Revising paragraph (b)(4).

The revision reads as follows:

§ 25.08 Qualifying activities value.

* * * * *

(b)* * *

(4) The quantified dollar value of qualifying activities that receive a multiplier under paragraphs (b)(2) or (b)(3) of this section may also be subject to an additional upward adjustment, for a maximum total upward adjustment of up to 4 times the quantified dollar value of the qualifying activity based on the OCC's or FDIC's determination of the activity's responsiveness, innovativeness, or complexity.

* * * * *

§ 25.09 [Amended]

■ 12. Section 25.09 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (a);
■ b. Removing the word ''it'' from paragraph (c)(2)(v) and adding in its place the phrase ''the bank'';
■ c. In paragraph (e):
■ i. Removing the phrase ''will consist'' from the first sentence and adding in its place the word ''consists''; and
■ ii. Adding the phrase ''assessed under the general performance standards in § 25.13'' after the word ''bank'' in the second sentence; and
■ d. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (g)

■ 13. Section 25.10 is amended by:

■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a) introductory text;
■ b. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(1)(i);
■ c. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(1)(ii);
■ d. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(1)(iii);
■ e. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(2)(i);
■ f. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(2)(ii);
■ g. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(2)(iii);
■ h. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(3)(i);
■ i. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(3)(ii);
■ j. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (a)(4);
■ k. Revising the last sentence of paragraph (b); and
■ l. Removing the word ''anticipates'' and adding the phrase ''and FDIC anticipate'' in paragraph (c).

The revision reads as follows:

§ 25.10 Performance standards and ratings, in general.

* * * * *

(b)* * *A small, intermediate, wholesale, or limited purpose bank that opts out from the general performance standards will be evaluated according to the performance standards described in paragraphs (a)(2) and (a)(3) of this section, as applicable, unless the bank is evaluated under an approved strategic plan as described under (a)(4) of this section.

* * * * *

§ 25.11 [Amended]

■ 14. Section 25.11 is amended by removing ''§ 25.08(c);'' in paragraph (c)(1) and adding ''§ 25.08(c)'' in its place.

§ 25.12 [Amended]

■ 15. Section 25.12 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a) introductory text;
■ b. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(1) introductory text;
■ c. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(2) introductory text;
■ d. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(3) introductory text;
■ e. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (c)(1) introductory text;
■ f. In paragraph (c)(2):
■ i. Adding the phrase ''or FDIC'' after ''OCC''; and
■ ii. Removing the phrase ''demographic borrower comparator or the associated'' and adding in its place ''borrower demographic comparator or the associated borrower'';
■ g. In paragraph (c)(3):
■ i. Adding the phrase ''or FDIC'' after ''OCC''; and
■ ii. Removing the phrase ''demographic borrower comparator or the associated'' and adding in its place ''borrower demographic comparator or the associated borrower'';
■ h. In paragraph (c)(4) introductory text:
■ i. Adding the phrase ''or FDIC'' after ''OCC''; and
■ ii. Removing the phrase ''demographic borrower comparator or the associated'' and adding in its place ''borrower demographic comparator or the associated borrower''.
■ 16. Section 25.13 is amended by:
■ a. Removing the word ''in'' and adding in its place ''in—'' in paragraph (c)(1)(ii)(B) introductory text;
■ b. Removing the word ''in'' and adding in its place ''in—'' in paragraph (c)(2)(ii)(A) introductory text;
■ c. Removing the word ''in'' and adding in its place ''in—'' in paragraph (c)(2)(ii)(B) introductory text;
■ d. Removing the phrase ''divided by'' in paragraph (c)(2)(iii) and adding ''*divided by*'' in its place;
■ e. Removing the phrase ''substantial noncompliance standard'' in paragraph (c)(4) and adding in its place the phrase ''substantial noncompliance performance standard'';
■ f. Removing the phrase ''average assessment area CRA evaluation measure'' in paragraph (d)(2)(ii) and adding in its place the phrase ''average annual assessment area CRA evaluation measure'';
■ g. Removing the phrase ''average assessment area CRA evaluation measure'' in paragraph (d)(3) and adding in its place the phrase ''average annual assessment area CRA evaluation measure'';
■ h. Removing the phrase ''average assessment area CRA evaluation measure'' in paragraph (d)(4) and adding in its place the phrase ''average annual assessment area CRA evaluation measure''; and
■ i. Adding paragraph (e).

The addition reads as follows:

§ 25.13 General performance standards and presumptive rating.

* * * * *

(e) *OCC approach to setting CRA evaluation measure benchmarks, retail lending distribution test thresholds, and community development minimums.* Based on the activity data collected from banks that are subject to the general performance standards, the OCC will calculate historic CRA activity levels and corresponding performance ratings under the general performance standards had they been in place. Based on this analysis, the OCC will set the CRA evaluation measure benchmarks, retail lending distribution test thresholds, and community development minimums such that the proportion of banks receiving hypothetical presumptive ratings of outstanding and satisfactory is no greater than the historical proportion of banks that received assigned ratings of outstanding and satisfactory.

§ 25.14 [Amended]

■ 17. Section 25.14 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(1);
■ b. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(2); and
■ c. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (d).

§ 25.15 [Amended]

■ 18. Section 25.15 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a);
■ b. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (b);
■ c. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (c) introductory text;
■ d. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (d)(1);
■ e. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (d)(2); and
■ f. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (e).
■ 19. Section 25.16 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a) introductory text;
■ b. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b) introductory text;
■ c. Removing the period at the end of paragraph (b)(3) and adding in its place a semicolon;
■ d. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(4);
■ e. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(5);
■ f. Removing the phrase ''*including for each assessment area.*'' in paragraph (c) and adding in its place the phrase ''including for each assessment area.''; and
■ g. Adding paragraph (d).

The addition reads as follows:

§ 25.16 Consideration of performance context.

* * * * *

(d) *Declines in CRA performance.* In assessing a bank's performance, the OCC

considers whether there has been a decline of 10% or greater in a bank's performance on the general performance standards as calculated based on historical data between the establishment of the objective benchmarks, thresholds, and minimums and the bank's first evaluation under the general performance standards. Declines that cannot be explained by market conditions or other factors under paragraph (b) of this section may warrant a downward adjustment in determining the bank's assigned rating.

§ 25.17 [Amended]

■ 20. Section 25.17 is amended by:
■ a. Adding the phrase ''or FDIC's'' after ''OCC's'' in paragraph (a) introductory text; and
■ b. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b).

§ 25.18 [Amended]

■ 21. Section 25.18 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a) introductory text;
■ b. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(1);
■ c. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a)(2);
■ d. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(2);
■ e. In paragraph (c):
■ i. Adding the phrase ''or FDIC's'' after ''OCC's'';
■ ii. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears;
■ f. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (d)(1);
■ g. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (e) introductory text;
■ h. Adding the phrase ''or FDIC's'' after ''OCC's'' in paragraph (e)(1);
■ i. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (f);
■ j. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (g)(3);
■ k. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (g)(4);
■ l. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (h)(1);
■ m. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (h)(2);
■ n. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (h)(3); and
■ o. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (i).

■ 22. Section 25.19 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' and removing the comma after ''§ 25.16'' in paragraph (a)(1); and
■ b. Revising paragraphs (a)(2) and (b).

The revisions read as follows:

§ 25.19 Assigned ratings.

(a)* * *

(2) *Assessment area assigned rating(s).* The OCC or FDIC determines the assessment area assigned rating(s) for a bank evaluated under § 25.13 based on its assessment area presumptive rating(s) under § 25.13, adjusted for performance context under § 25.16 and consideration of discriminatory or other illegal credit practices under § 25.17.

(b) *Strategic plans assigned rating(s).* A bank operating under a strategic plan will receive, as applicable, an assigned rating, assessment area assigned rating(s), and state-level and multistate metropolitan statistical area assigned rating(s) of satisfactory or outstanding if it has met the measurable goals in the plan that correspond to those ratings after considering performance context under § 25.16 and discriminatory or other illegal credit practices under § 25.17.

§ 25.20 [Amended]

■ 23. Section 25.20 is amended by:
■ a. Removing the phrase ''assigned rating'' from the heading and adding in its place the phrase ''assigned rating(s)''; and
■ b. Adding the phrase ''or FDIC'' after ''OCC''.

§ 25.21 [Amended]

■ 24. Section 25.21 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a);
■ b. Removing the phrase ''evaluated in the assessment area'' and adding in its place the phrase ''evaluated in each assessment area'' in paragraph (b)(1);
■ c. Removing the phrase ''paragraph (c)(8) of this section'' in paragraph (c)(1) introductory text and adding in its place the phrase ''paragraph (c)(9) of this section'';
■ d. In paragraph (c)(7):
■ i. Redesignating paragraphs (c)(7)(iii) through (viii) as paragraphs (c)(7)(iv) through (ix); and
■ ii. Redesignating the second instance of paragraph (c)(7)(ii) as paragraph (c)(7)(iii);
■ e. Removing the phrase ''qualifies under § 25.04(a)(1)(3)'' in paragraph (c)(9) introductory text and adding in its place the phrase ''qualifies under § 25.04(a)(3)''; and
■ f. Removing the phrase ''on the date'' in paragraph (c)(9)(vii) and adding in its place the word ''conducted''.

§ 25.23 [Amended]

■ 25. Section 25.23 is amended by:
■ a. Removing the phrase ''*community development service required*'' in the paragraph (b) heading and adding in its place ''*community development service data required*''; and
■ b. Removing the phrase ''qualifies under § 25.04(d)'' in paragraph (b)(4) introductory text and adding in its place the phrase ''qualifies under § 25.04(a)(3)''.

§ 25.25 [Amended]

■ 26. Section 25.25 is amended by adding the phrase ''or FDIC'' after ''OCC''.

§ 25.26 [Amended]

■ 27. Section 25.26 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a);
■ b. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(1)(i) introductory text;
■ c. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(1)(ii) introductory text;
■ d. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(1)(iii);
■ e. In paragraph (c):
■ i. Adding the phrase ''or FDIC'' after ''OCC''; and
■ ii. Removing ''§ 25.21(e)'' and adding in its place ''§ 25.23(d)''.

■ 28. Section 25.27 is amended in paragraph (b) by:
■ a. Removing in the introductory text the phrase ''subject to reporting under this part'' and adding in its place the phrase ''evaluated under § 25.13'';
■ b. Redesignating paragraphs (b)(2) through (10) as paragraphs (b)(3) through (11); and adding a new paragraph (b)(2).

The addition reads as follows:

§ 25.27 Public disclosures.

* * * * *

(b) * * *

(2) The number of home mortgage loans in low- and moderate-income census tracts;

* * * * *

§ 25.28 [Amended]

■ 29. Section 25.28 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' wherever it appears in paragraph (a)(2); and
■ b. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(1).

§ 25.29 [Amended]

■ 30. Section 25.29 is amended by adding the phrase ''or FDIC'' after ''OCC''.

Appendix A to Part 25 [Amended]

■ 31. Appendix A to part 25 is amended by:
■ a. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (a);

■ b. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(1)(i) introductory text;
■ c. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(2)(i);
■ d. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(2)(ii);
■ e. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (b)(3)(ii)(B);
■ f. Removing the phrase ''assigned rating'' after ''substantial noncompliance'' in paragraph (b)(3)(iii);
■ g. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (c) introductory text;
■ h. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (c)(1) introductory text;
■ i. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (c)(2) introductory text;
■ j. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (c)(3) introductory text; and
■ k. Adding the phrase ''or FDIC'' after ''OCC'' in paragraph (c)(4) introductory text.
■ 32. Revise appendix B to part 25 to read as follows:

Appendix B to Part 25—Community Reinvestment Act Notice

Under the Federal Community Reinvestment Act (CRA), the [Office of the Comptroller of the Currency (OCC) or Federal Deposit Insurance Corporation (FDIC)] evaluates our record of helping to meet the credit needs of this community, consistent with safe and sound operations. The [OCC or FDIC] also takes this record into account when deciding on certain applications submitted by us.

Your involvement is encouraged.

You are entitled to certain information about our operations and our performance under the CRA, including, for example, information about our branches, such as their location and services provided at them; the public section of our most recent CRA Performance Evaluation, prepared by the [OCC or FDIC]; and comments received from the public relating to assessment area needs and opportunities, as well as our responses to those comments. You may review this information today by reviewing the public file which is available at (web address and/or physical address at which the public file can be reviewed and copied).

You may also have access to the following additional information, which we will make available to you after you make a request to us: (1) A map showing the assessment area containing a select branch, which is the area in which the [OCC or FDIC] evaluates our CRA performance for that particular community; (2) branch addresses and associated branch facilities and hours in any assessment area; (3) a list of services we provide at those locations; (4) our most recent rating in the assessment area; and (5) copies of all written comments received by us that specifically relate to the needs and opportunities of a given assessment area, and any responses we have made to those comments. If we are operating under an approved strategic plan, you may also have access to a copy of the plan.

At least 30 days before the beginning of each quarter, the [OCC or FDIC] publishes a nationwide list of the (entity type) that are scheduled for CRA examination in that quarter. This list is available from the [OCC Deputy Comptroller (address) or FDIC appropriate regional director (address)]. You may send written comments regarding the needs and opportunities of any of the (entity type)'s assessment area(s) to (name, address, and email address of official at bank) and [OCC Deputy Comptroller (address and email address) or FDIC appropriate regional director (address and email address)]. Your comments, together with any response by us, will be considered by the [OCC or FDIC] in evaluating our CRA performance and may be made public.

You may ask to look at any comments received by the [OCC Deputy Comptroller or FDIC appropriate regional director]. You may also request from the [OCC Deputy Comptroller or FDIC appropriate regional director] an announcement of our applications covered by the CRA filed with the [OCC or FDIC]. [(We are an affiliate of (name of holding company), a (entity type) holding company. You may request from the (title of responsible official), Federal Reserve Bank of _____(address) an announcement of applications covered by the CRA filed by (entity type) holding companies.)]

Appendix C to Part 25 [Amended]

■ 33. Appendix C to part 25 is amended by:

■ a. Removing the phrase ''pursuant part 1003 of this title'' in § 25.43(b)(2) and adding in its place the phrase ''pursuant to part 1003 of this title''; and

■ b. Removing the phrase ''pursuant part 1003 of this title'' in § 195.43(b)(2) and adding in its place the phrase ''pursuant to part 1003 of this title''.

PART 35—DISCLOSURE AND REPORTING OF CRA–RELATED AGREEMENTS

■ 34. The authority citation for part 35 continues to read as follows:

Authority: 12 U.S.C. 1, 93a, 1462a, 1463, 1464, 1831y, and 5412(b)(2)(B).

§ 35.1 [Amended]

■ 35. Section 35.1 is amended by removing the phrase ''or part 195 (Community Reinvestment)'' from paragraph (c).
■ 36. Section 35.4 is amended by revising paragraph (a)(2).

The revision reads as follows:

§ 35.4 Fulfillment of the CRA.

(a)* * *

(2) *Activities given favorable CRA consideration.* Performing any of the following activities if the activity is of the type that is likely to receive favorable consideration by a Federal banking agency in evaluating the performance under the CRA of the insured depository institution that is a party to the agreement or an affiliate of a party to the agreement—

(i) Retail loans, community development loans, community development investments, and community development services, as described in § 25.04 (12 CFR 25.04) or 12 CFR part 25, Appendix C, § 25.22 or § 25.23, as applicable;

(ii) Delivering retail banking services, as described in 12 CFR part 25, Appendix C, § 25.24(d);

(iii) In the case of a wholesale or limited-purpose insured depository institution, community development lending, including originating and purchasing loans and making loan commitments and letters of credit, making community development investments, or providing community development services, as described in § 25.15(c) (12 CFR 25.15(c)) or 12 CFR part 25, Appendix C, § 25.25(c), as applicable;

(iv) In the case of a small insured depository institution, any lending or other activity described in § 25.14(a) (12 CFR 25.14(a)) or 12 CFR part 25, Appendix C, § 25.26(a), as applicable; or

(v) In the case of an insured depository institution that is evaluated on the basis of a strategic plan, any element of the strategic plan, as described in § 25.18(g) (12 CFR 25.18(g)) or 12 CFR part 25, Appendix C, § 25.27(f), as applicable.

* * * * *

■ 37. Effective January 1, 2024, revise paragraph (a)(2) to read as follows:

§ 35.4 Fulfillment of the CRA.

(a)* * *

(2) *Activities given favorable CRA consideration.* Performing any of the following activities if the activity is of the type that is likely to receive favorable consideration by a Federal banking agency in evaluating the performance under the CRA of the insured depository institution that is a party to the agreement or an affiliate of a party to the agreement—

(i) Retail loans, community development loans, community development investments, and community development services, as described in § 25.04 (12 CFR 25.04);

(ii) In the case of a wholesale or limited-purpose insured depository institution, community development lending, including originating and purchasing loans and making loan commitments and letters of credit, making community development investments, or providing community development services, as described in § 25.15(c) (12 CFR 25.15(c));

(iii) In the case of a small insured depository institution, any lending or other activity described in § 25.14(a) (12 CFR 25.14(a)); or

(iv) In the case of an insured depository institution that is evaluated on the basis of a strategic plan, any element of the strategic plan, as described in § 25.18(g) (12 CFR 25.18(g)).

* * * * *

§ 35.6 [Amended]

■ 38. Section 35.6 is amended by removing the phrase ''set forth in § 25.43 (12 CFR 25.43)'' in paragraph (b)(7) and adding in its place ''set forth in § 25.28 (12 CFR 25.28) or 12 CFR part 25, Appendix C, § 25.43, as applicable''.

§ 35.11 [Amended]

■ 39. Section 35.11 is amended by removing the phrase ''described in § 25.43 (12 CFR 25.43)'' in paragraph (d) and adding in its place the phrase ''described in § 25.28 (12 CFR 25.28) or 12 CFR part 25, Appendix C, § 25.43, as applicable''.

PART 192—CONVERSIONS FROM MUTUAL TO STOCK FORM

■ 40. The authority citation for part 192 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 2901 *et seq.,* 5412(b)(2)(B); 15 U.S.C. 78c, 78l, 78m, 78n, 78w.

§ 192.200 [Amended]

■ 41. Section 192.200 is amended by removing the phrase ''under 12 CFR part 195'' in paragraph (c) introductory text and adding in its place ''under part 25''.

Brian P. Brooks,

Acting Comptroller of the Currency.

[FR Doc. 2020–26394 Filed 12–3–20; 8:45 am]

BILLING CODE 4810–33–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 741

[NCUA 2020–0114]

RIN 3133–AF30

Capitalization of Interest in Connection With Loan Workouts and Modifications

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) seeks public comment on a proposed rule to amend its regulations by removing the prohibition on the capitalization of interest in connection with loan workouts and modifications. The Board has determined that the current prohibition on authorizing additional advances to finance unpaid interest may be overly burdensome and, in some cases, hamper a federally insured credit union's (FICU's) good-faith efforts to engage in loan workouts with borrowers facing difficulty because of the economic disruption that the COVID–19 pandemic has caused. Advancing interest may avert the need for alternative actions that would be more harmful to borrowers. The proposed rule would establish documentation requirements to help ensure that the addition of unpaid interest to the principal balance of a mortgage loan does not hinder the borrower's ability to become current on the loan. The proposed change would apply to workouts of all types of member loans, including commercial and business loans. The Board has also taken this opportunity to make several technical changes to the Appendix to improve its clarity and update certain references. For the convenience of readers, the Board is republishing the Appendix in its entirety so that the changes may be viewed in the context of the full document.

DATES: Comments must be received on or before February 2, 2021.

ADDRESSES: You may submit written comments, identified by RIN 3133–AF30, by any of the following methods (*Please send comments by one method only*):

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments for NCUA 2020–0114.
- *Fax:* (703) 518–6319. Include ''[Your Name]—Comments on ''Proposed Rule: Capitalization of Interest in Connection with Loan Workouts and Modifications'' in the transmittal.
- *Mail:* Address to Melane Conyers-Ausbrooks, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

Public Inspection: You may view all public comments on the Federal eRulemaking Portal (*http://www.regulations.gov*) as submitted, except for those we cannot post for technical reasons. The NCUA will not edit or remove any identifying or contact information from the public comments submitted. Due to social distancing measures in effect, the usual opportunity to inspect paper copies of comments in the NCUA's law library is not currently available. After social distancing measures are relaxed, visitors may make an appointment to review paper copies by calling (703) 518–6540 or emailing *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Scott Neat, Associate Director of the Office of Examination and Insurance, at (703) 518–6360; and Ariel Pereira and Gira Bose, Staff Attorneys, Office of General Counsel, at (703) 518–6540.

SUPPLEMENTARY INFORMATION:

I. Background

A. May 2012 Adoption of the Loan Workout and Accrual and TDR Requirements

In May 2012, the Board published a final rule on loan workout policies and monitoring requirements that applies to all FICUs. The rule also established requirements for nonaccrual policies, and for regulatory reporting of troubled debt restructurings (TDRs).[1] The Board noted that the May 2012 final rule was similar to guidance set forth in an interagency policy statement issued by the banking agencies of the Federal Financial Institutions Examination Council (FFIEC) on June 12, 2000,[2] though the NCUA did not join the agencies in issuing the statement.

The May 2012 final rule, codified in Appendix B to Part 741 of the NCUA's

[1] 77 FR 31993 (May 31, 2012).

[2] FFIEC, Uniform Retail Credit Classification and Account Management Policy, 65 FR 36903 (June 12, 2000).

regulations, established four requirements.

1. The final rule required that FICUs have written policies that address loan workouts and nonaccrual practices required under § 741.3, Criteria. In Appendix B, the Board also required that such policies prohibit a credit union from authorizing additional advances to a borrower to finance unpaid interest (capitalization of interest) and credit union fees. Credit unions are permitted to make such advances to cover third-party fees, excluding credit union commissions, such as force-placed insurance and property taxes. This requirement is similar to the expectation established in the June 2000 interagency statement of policy cited above, except that the interagency statement provided that a bank's policies should prohibit such advances but did not state that the policies must prohibit them.

2. The final rule standardized an industry-wide practice by requiring that FICUs cease to accrue interest on all loans at 90 days or more past due, subject to a few exceptions.

3. The final rule required that a FICU maintain member business workout loans in a nonaccrual status until it receives six consecutive payments under the modified terms.

4. The final rule required that FICUs calculate and report TDR loan delinquency based on restructured contract terms, rather than the original loan terms.

In adopting the May 2012 final rule, the Board stated its intention to provide regulatory relief to FICUs while instituting countervailing controls and clarifying regulatory expectations. In the 2012 rulemaking, the Board acknowledged the need to balance appropriate loan workout programs with safety and soundness considerations. The Board noted that such considerations include the ability to identify deterioration in the quality of the loan portfolio and delayed loss recognition in light of the high degree of relapse into past due status.

B. COVID–19 Pandemic and FFIEC Statement on Loan Accommodations

In light of the challenges and economic disruption caused by the COVID–19 pandemic, the Board is proposing an amendment to the requirement in the May 2012 final rule that relates to the capitalization of interest.[3] As the NCUA and other member agencies of the FFIEC noted in an August 2020 statement on loan accommodations, the COVID–19 pandemic has had a significant adverse impact on consumers, businesses, financial institutions, and the economy.[4]

To address such impacts, the Coronavirus Aid, Relief, and Economic Security (CARES) Act[5] provided several forms of relief to businesses and borrowers, and some states and localities have provided similar credit accommodations. Additionally, many financial institutions have voluntarily offered borrowers other credit accommodations.

The NCUA, along with the other FFIEC members, has encouraged financial institutions to work prudently with borrowers who are unable, or may become unable, to meet their contractual payment obligations as a result of the COVID–19 pandemic.[6] Specifically, the NCUA and the other FFIEC members have stated that they view loan accommodations as positive actions that can mitigate adverse effects on borrowers caused by the COVID–19 pandemic. For borrowers experiencing financial hardship, a prudently underwritten and appropriately managed loan modification, consistent with safe and sound lending practices, is generally in the long-term best interest of both the borrower and the credit union. Such modifications may allow a borrower to remain in their home or a commercial borrower to maintain operations due to external circumstances, and can help credit unions minimize the costs of default and foreclosures.

While some borrowers will be able to resume contractual payments at the end of an accommodation, others may be unable to meet their obligations due to continuing financial challenges. In light of these challenges, the NCUA and the other FFIEC members encouraged financial institutions to consider prudent accommodation options that are based on an understanding of a borrower's credit risk. Accommodations must also be consistent with applicable laws and regulations and ease cash flow pressures to improve the affected borrower's ability to service debt, which improves a financial institution's ability to collect on its loans. The agencies noted that such arrangements also may reduce financial stress on borrowers by decreasing delinquencies or other adverse consequences. Imprudent relief practices by a lender can adversely affect borrowers and expose financial institutions to increases in credit, compliance, reputational, operational, and other risks. Additionally, imprudent relief practices present risks to a financial institution's capital position.

C. Capitalization of Unpaid Interest

During development of the interagency guidance discussed above, the Board determined that the prohibition in the May 2012 final rule on the capitalization of interest might be overly burdensome and, in some cases, possibly hamper a FICU's good-faith efforts to engage in loan workouts with borrowers facing difficulty because of the economic disruption caused by the COVID–19 pandemic.

Banks are not subject to the same prohibition on capitalizing interest (the banking agencies have not adopted an absolute standard equivalent to the rule that the Board codified in 2012). The banking agencies have addressed capitalization of interest through guidance, letters, and Call Report instructions, none of which strictly prohibit the capitalization of interest when modifying loans. Instead, the banking agencies examine these practices for safety and soundness during the course of their supervision. As a result, FICUs have fewer options when working with their member borrowers, as compared to banks.

Further, the government-sponsored enterprises (GSEs), Fannie Mae and Freddie Mac, have had a long-standing policy supporting the ability of servicers to capitalize interest and fees as part of a prudent modification program. When FICUs originate certain loans, they often do so with the intent of selling to the secondary market for liquidity or other strategic purposes, but many FICUs may retain servicing rights after the sale of the loan. The GSEs are frequent investors in FICU-originated loans. After such a sale, if a member with a loan sold by a FICU begins experiencing financial difficulty and needs assistance in the form of a modification, capitalization of interest is permitted within a loan workout by the GSE that now holds the loan. However, for loans retained by the FICU, the borrower would not get the benefit of interest capitalization upon a loan workout due to the prohibition currently in the Appendix. This contrast

[3] The coronavirus disease 2019 outbreak was declared a national emergency under Proclamation 9994, 85 FR 15337 (Mar. 18, 2020).

[4] *Joint Statement on Additional Loan Accommodations Related to COVID–19,* available at *https://www.ncua.gov/files/press-releases-news/joint-statement-additional-loan-accommodations.pdf.*

[5] Public Law 116–136, 134 Stat. 281 (Mar. 27, 2020).

[6] *See* Interagency Statement on Loan Modifications and Reporting for Financial Institutions Working with Customers Affected by the Coronavirus (Revised), (Apr. 7, 2020) and FFIEC's Joint Statement on Additional Loan Accommodations Related to COVID–19 (Aug. 3, 2020).

with the GSEs' policy results in inequitable treatment of members within the same FICU, which jeopardizes the integrity of the cooperative membership base.

For the reasons described in the preceding discussion, the Board believes the current rule's prohibition on the capitalization of interest limits a FICU's options to implement a mutually beneficial solution that addresses the potential financial challenge of their members when the forbearance period ends. As discussed in greater detail in the Summary of the Proposed Rule, the Board proposes to remove the prohibition on capitalization of interest from Appendix B. As noted, the Board's reconsideration was partially prompted by the economic impact of the COVID–19 pandemic and related developments. Other considerations described above, such as parity with the treatment of interest capitalization by banks, have also factored in the Board's determination. Accordingly, the Board believes it is appropriate to propose amending Appendix B to make capitalization of interest a permissible option indefinitely. Despite proposing this change, the Board underscores that Appendix B currently requires several safety and soundness and consumer protection-oriented measures that would also apply to this practice. Furthermore, capitalization of interest is not an appropriate solution in all cases and, as the Appendix currently provides, a FICU should consider and balance the best interests of the credit union and the borrower. In addition, the Board proposes to add several consumer protection and safety and soundness requirements to the Appendix for FICUs that capitalize interest in connection with loan workouts.

II. Legal Authority

The Board issues this proposed rule pursuant to its authority under the Federal Credit Union (FCU) Act.[7] Under the FCU Act, the NCUA is the chartering and supervisory authority for FCUs and the Federal supervisory authority for FICUs.[8] The FCU Act grants the NCUA a broad mandate to issue regulations that govern both FCUs and FICUs. Section 120 of the FCU Act is a general grant of regulatory authority and authorizes the Board to prescribe rules and regulations for the administration of the FCU Act.[9] Section 209 of the FCU Act is a plenary grant of regulatory authority to the NCUA to issue rules and regulations necessary or appropriate to carry out its role as share insurer for all FICUs.[10] Accordingly, the FCU Act grants the Board broad rulemaking authority to ensure that the credit union industry and the National Credit Union Share Insurance Fund remain safe and sound.

III. Summary of the Proposed Rule

A. Capitalization of Interest

The Board is proposing to amend a prescriptive requirement in its regulations by amending Appendix B of Part 741 to remove the prohibition on the capitalization of interest in connection with loan workouts and modifications. The proposed change would apply to workouts of all types of member loans, including commercial and business loans. The NCUA also notes that—consistent with the scope of Appendix B—the proposed change addresses the capitalization of interest in connection with loan modifications. The proposed rule, however, does not address the capitalization of interest that may occur in other contexts. The Board notes that banks frequently include interest capitalization as one of several components in a loan restructuring to mutually benefit the lender and the borrower. The Board expects that FICUs will follow suit, and provide borrowers with the option to capitalize interest along with other loan modification options, such as the lowering of loan payments or the interest rate, extending the maturity date, partial principal or interest forgiveness and other modifications.

The proposed rule would add a definition of capitalized interest to the Glossary of Appendix B. For the purposes of this rulemaking, capitalization of interest constitutes the addition of accrued but unpaid interest to the principal balance of a loan. This differs from ceasing to accrue interest on past-due loans, generally when the loan reaches 90 days past due.

The rule will continue to provide that a credit union may, in no event, authorize additional advances to finance credit union fees and commissions. FICUs will be permitted to continue to make advances to cover third party fees to protect loan collateral, such as force-placed insurance or property taxes. The Board believes that maintaining the prohibition on the capitalization of credit union fees is an important consumer protection feature of the rule for member borrowers.

Prior to 2012, NCUA guidance contemplated capitalization of interest and fees as one of many options available to credit unions to modify a loan to accommodate a borrower's circumstances. In the 2012 final rule, the Board adopted a requirement that a FICU's loan workout policy prohibit additional advances to finance unpaid interest and fees. The final rule did allow such advances to finance third-party fees, which was in response to a request by a commenter on the proposed rule. The 2012 final rule did not explain the reasons this practice was prohibited. The Board has reconsidered the conclusion from the 2012 final rule and proposes to remove the prohibition on the capitalization of interest because, when used appropriately, capitalization of interest may be in the best interests of both a FICU and the borrower. Accordingly, the proposed rule would delete this prohibition from Appendix B.

The Board underscores that in proposing to remove this prohibition, it would maintain several requirements that apply to all loan workout policies in Appendix B. For example, the Appendix establishes the expectation that loan workouts will consider and balance the best interests of the FICU and the borrower, including consumer financial protection measures. Ensuring the best interest of the borrower prohibits predatory type lending practices such as including loan terms that result in negative amortization. In addition, a FICU's policy must establish limits on the number of modifications allowed for an individual loan. Further, the policy must ensure that a FICU make loan workout decisions based on a borrower's renewed willingness and ability to repay the loan.

If a FICU restructures a loan more frequently than once a year or twice in five years, examiners will have higher expectations for the documentation of the borrower's renewed willingness and ability to repay the loan. The current Appendix also sets forth several supervisory expectations relating to multiple restructurings, stating that examiners will request validation documentation regarding collectability if a FICU engages in multiple restructurings of a loan. The current Appendix also requires that a FICU maintain sufficient documentation to demonstrate that the FICU's personnel communicated the new terms with the borrower, that the borrower agreed to pay the loan in full under the new terms and, most importantly, the borrower has the ability to repay the loan under any new terms.

These requirements and expectations, which currently apply to FICUs' loan workout policies, would apply equally if a FICU adopts a practice of

[7] 12 U.S.C. 1751 *et al.*

[8] 12 U.S.C. 1752–1775.

[9] 12 U.S.C. 1766(a).

[10] 12 U.S.C. 1789(a)(11).

capitalizing interest in connection with loan workouts. In addition, in light of the potential for this practice to have a detrimental effect on borrowers if executed inappropriately, and to mask the true financial status of a loan and a credit union's financial statements, the Board proposes to add requirements to the Appendix to apply to FICUs that engage in this practice.

Modifications of loans that result in capitalization of unpaid interest are appropriate only when the borrower has the ability to repay the debt in accordance with the modification. At a minimum, if a FICU's loan modification policy permits capitalization of unpaid interest, the policy must require each of the following:

1. Compliance with all applicable consumer protection laws and regulations, including, but not limited to, the Equal Credit Opportunity Act, the Fair Housing Act, the Truth In Lending Act, the Real Estate Settlement Procedures Act, the Fair Credit Reporting Act, and the prohibitions against the use of unfair, deceptive or abusive acts or practices contained in the Consumer Financial Protection Act of 2010. (The Board notes that FICUs are also expected to comply with applicable State consumer protection laws that, in some instances, may be more stringent than Federal law, prohibiting, for example, the charging of interest on interest.)

2. Documentation that reflects a borrower's ability to repay, a borrower's source(s) of repayment, and when appropriate, compliance with the FICU's valuation policies at the time the modification is approved.

3. Providing borrowers with documentation that is accurate, clear, and conspicuous and consistent with Federal and state consumer protection laws.

4. Appropriate reporting of loan status for modified loans in accordance with applicable law and accounting practices. The FICU shall not report a modified loan as past due if the loan was current prior to modification and the borrower is complying with the terms of the modification.

5. Prudent policies and procedures to help borrowers resume affordable and sustainable repayments that are appropriately structured, while at the same time minimizing losses to the credit union. The prudent policies and procedures must consider:

i. Whether the loan modifications are well-designed, consistently applied, and provide a favorable outcome for borrowers.

ii. The available options for borrowers to repay any missed payments at the end of their modifications to avoid delinquencies or other adverse consequences.

6. Appropriate safety and soundness safeguards to prevent the following:

i. Masking deteriorations in loan portfolio quality and understating charge-off levels;

ii. Delaying loss recognition resulting in an understated allowance for loan and lease losses account or inaccurate loan valuations;

iii. Overstating net income and net worth (regulatory capital) levels; and

iv. Circumventing internal controls.

B. Technical Updates to Appendix B

The Board has also taken this opportunity to make several technical changes to the Appendix to improve its clarity and update certain references. For example, the Board is proposing several updates to references to the NCUA's or other guidance in the Appendix, such as guidance or standards issued by other federal banking agencies or the Financial Accounting Standards Board (FASB). These changes are intended to provide more current information, and are not intended to entail substantive policy changes within the Appendix.

In May 2014, FASB issued an accounting standards update for revenue recognition (ASU 2014–09) which replaced the cost recovery method of income recognition in ASC 605–10–25–4 with transition guidance found in ASC 606—Revenue from Contracts with Customers. The (2012) Appendix made reference to the cost recovery method of income recognition with citation in the Glossary. As this has been superseded by ASC 606, the Board eliminated this reference in the Appendix and emphasizes that accrual of interest income ceases on a financial asset when full payment of principal and interest in cash is not expected.

In addition, to conform to the terminology that the Board adopted in 2016 in amending part 723,[11] the Board proposes to update references to member business loans to also refer to commercial loans. These changes are not intended to create new requirements or standards.

The Board also proposes to make terminology in the Appendix consistent with its purpose. The Appendix sets forth requirements for FICU policies relating to loan workouts, TDRs, and nonaccrual status. In several instances, the current Appendix uses the word ''should'' when referring to necessary elements of a FICU's policies or refers to the Appendix as ''guidance'' or an interpretive ruling and policy statement. To make the purpose and effect of the Appendix clearer, the Board proposes using mandatory language where appropriate and eliminating references to the Appendix as ''guidance.''

Finally, the Board proposes to clarify several statements of the Appendix to make it more consistent with plain language principles. The Board does not intend to make any substantive changes in these amendments. The **Federal Register**'s publication procedures require the Board to print the entire revised Appendix in the amendatory instructions of this proposed rule. To help commenters follow the proposed changes, the NCUA will post a document on its website that shows the specific proposed changes in redline or strikethrough form.

C. NCUA Questions for Comment

The NCUA is interested in all aspects of the interest capitalization issue. In addition to offering your comments on any aspect of this proposed rule, please provide your input on the following questions:

1. What was your experience or level of use with interest capitalization before the agency prohibited the practice in 2012 pursuant to Appendix B?

2. How likely are you to incorporate interest capitalization as a mortgage modification tool if permitted by the agency?

3. What risks do you foresee, if any, to either the credit union or the borrower in a mortgage modification that includes capitalization of interest?

4. When credit unions originate certain loans, they often do so with the intent of selling to the secondary market. The GSEs are frequent investors in credit union originated loans. Subsequent to sale, if a member with a loan sold by a credit union begins experiencing financial difficulty and needs assistance in the form of a modification, capitalization of interest is permitted within a loan workout by the GSE who now holds the loan. However, Fannie Mae does not permit interest capitalization *prior* to sale and Freddie Mac does so only under certain conditions. How would this limitation on capitalizing interest prior to sale to a GSE impact your willingness or ability to offer interest capitalization on a loan?

5. In light of the fact that adding unpaid interest to the principal balance of a mortgage loan could potentially be detrimental to a member's ability to become current on the loan, the NCUA is proposing to add a number of consumer protection guardrails to Appendix B. We invite comments on these guardrails. In addition, what other

[11] 81 FR 13530 (Mar. 14, 2016).

documentation, disclosure, or other consumer protection features, if any, should the NCUA require before permitting capitalization of interest as a loan modification tool? Are the consumer protections that apply to other types of loan modification sufficient to protect borrowers who receive interest capitalization or should the agency consider any other protections to counter any risks caused specifically by interest capitalization?

6. The proposed rule continues to provide that a credit union may, in no event, authorize additional advances to finance credit union fees and commissions. Should the Board authorize the capitalization of such fees and commissions at the final rule stage? Why or why not? Depending on the information obtained through the rulemaking, the Board may consider making this change in the final rule.

IV. Regulatory Procedures

A. Regulatory Flexibility Act

The Regulatory Flexibility Act [12] generally requires that, in connection with a notice of proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities. A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the Regulatory Flexibility Act to include FICUs with assets less than $100 million) and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule. The proposed rule would allow FICUs to capitalize unpaid interest when working with borrowers. The proposed rule is not expected to increase the cost burden for FICUs. Accordingly, the NCUA certifies that the proposed rule will not have a significant economic impact on a substantial number of small credit unions.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden.[13] For purposes of the PRA, a paperwork burden may take the form of a reporting, recordkeeping, or a third-party disclosure requirement, referred to as an information collection. The NCUA proposes to amend Appendix B of Part 741 to remove the prohibition on the capitalization of interest in connection with loan workouts and modifications and to allow FICUs to capitalize unpaid interest when working with borrowers. Currently, all FICUs are required to retain and maintain a written loan policy; of which 500 FICUs are estimated to take four hours annually to retain and maintain enhanced records related to loan workout activity. NCUA anticipates a 50 percent increase in the number of these respondents due to the amendments in this proposed rule. Information collection requirements prescribed by Appendix B to 741 are currently approved under OMB control number 3133–0092. This revision of a currently approved collection would increase the information collection requirements by 2,000 burden hours.

OMB Control Number: 3133–0092.

Title of information collection: Loans to Members and Lines of Credit to Members, 12 CFR 701.21 and Appendix B to 741.

Estimated number of respondents: 5,236.

Estimated number of responses per respondent: 4.5.

Estimated total annual responses: 23,534.

Estimated burden per response: 1.0.

Estimated total annual burden: 23,584.

The NCUA invites comments on: (a) 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; (b) 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) ways to enhance the quality, utility and clarity of the information to be collected; and (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; and (e) estimates of capital or start-up costs and cost of operation, maintenance, and purchase of services to provide information.

All comments are a matter of public record. Due to the limited in-house staff, email comments are preferred. Comments regarding the information collection requirements of this rule should be (1) mailed to: *PRAcomments@ncua.gov* with ''OMB No. 3133–0133'' in the subject line; faxed to (703) 837–2406; or mailed to Dawn Wolfgang, NCUA PRA Clearance Officer, National Credit Union Administration, 1775 Duke Street, Suite 6032, Alexandria, VA 22314, and to the (2) Office of Information and Regulatory Affairs, Office of Management and Budget, at *www.reginfo.gov/public/do/PRAMain.* Select ''Currently under 30-day Review—Open for Public Comments'' or use the search function.

C. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, the NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. This rulemaking will not have a substantial direct effect on the states, on the connection between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The NCUA has determined that this proposal does not constitute a policy that has federalism implications for purposes of the executive order.

D. Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.[14]

List of Subjects in 12 CFR Part 741

Credit, Credit unions, Share insurance.

By the National Credit Union Administration Board on November 19, 2020.

Melane Conyers-Ausbrooks,

Secretary of the Board.

For the reasons discussed in the preamble, the Board proposes to amend 12 CFR part 741 as follows:

PART 741—REQUIREMENTS FOR INSURANCE

■ 1. The authority citation for part 741 continues to read as follows:

Authority: 12 U.S.C. 1757, 1766(a), 1781–1790, and 1790d; 31 U.S.C. 3717.

■ 2. Appendix B to part 741 is revised to read as follows:

[12] 5 U.S.C. 603(a).

[13] 44 U.S.C. 3507(d); 5 CFR part 1320.

[14] Public Law 105–277, 112 Stat. 2681 (1998).

Appendix B to Part 741—Loan Workouts, Nonaccrual Policy, and Regulatory Reporting of Troubled Debt Restructured Loans

This appendix establishes requirements for the management of loan *workout* [1] arrangements, loan nonaccrual, and regulatory reporting of *troubled debt restructured loans* (herein after referred to as TDR or TDRs). This appendix applies to all federally insured credit unions.

Under this appendix, TDRs are as defined in *generally accepted accounting principles (GAAP),* and the Board does not intend to change the Financial Accounting Standards Board's (FASB) definition of TDR in any way through this policy. In addition to existing agency policy, this appendix sets the NCUA's supervisory expectations governing loan workout policies and practices and loan accruals.

Written Loan Workout Policy and Monitoring Requirements [2]

For purposes of this appendix, types of workout loans to borrowers in financial difficulties include *re-agings, extensions, deferrals, renewals, or rewrites.* See the Glossary entry on workouts for further descriptions of each term. Borrower retention programs or *new loans* are not encompassed within this policy nor considered by the Board to be workout loans.

A credit union can use loan workouts to help borrowers overcome temporary financial difficulties such as loss of job, medical emergency, or change in family circumstances such as the loss of a family member. Loan workout arrangements must consider and balance the best interests of both the borrower and the credit union.

The lack of a sound written policy on workouts can mask the true performance and *past due* status of the loan portfolio. Accordingly, the credit union board and management must adopt and adhere to an explicit written policy and standards that control the use of loan workouts, and establish controls to ensure the policy is consistently applied. The loan workout policy and practices should be commensurate with a credit union's size and complexity, and must conform with a credit union's broader risk mitigation strategies. The policy must define eligibility requirements (that is, under what conditions the credit union will consider a loan workout), including establishing limits on the number of times an individual loan may be modified.[3] The policy must also ensure credit unions make loan workout decisions based on a borrower's renewed willingness and ability to repay the loan. If a credit union restructures a loan more frequently than once a year or twice in five years, examiners will have higher expectations for the documentation of the borrower's renewed willingness and ability to repay the loan. The NCUA is concerned about restructuring activity that pushes existing losses into future reporting periods without improving a loan's collectability. One way a credit union can provide convincing evidence that multiple restructurings improve collectability is to validate completed multiple restructurings that substantiate the claim. Examiners will ask for such validation documentation if a credit union engages in multiple restructurings of a loan.

In addition, the policy must establish sound controls to ensure loan workout actions are appropriately structured.[4] The policy must explicitly prohibit the authorization of additional advances to finance credit union fees and commissions. The credit union may, however, make advances to cover third-party fees, such as force-placed insurance or property taxes. For loan workouts granted, a credit union must document the determination that the borrower is willing and able to repay the loan.

Modifications of loans that result in capitalization of unpaid interest are appropriate only when a borrower has the ability to repay the debt. At a minimum, if a FICU's loan modification policy permits capitalization of unpaid interest, the policy must require:

1. Compliance with all applicable federal and state consumer protection laws and regulations, including, but not limited to, the Equal Credit Opportunity Act, the Fair Housing Act, the Truth In Lending Act, the Real Estate Settlement Procedures Act, the Fair Credit Reporting Act, and the prohibitions against the use of unfair, deceptive or abusive acts or practices in the Consumer Financial Protection Act of 2010.

2. Documentation that reflects a borrower's ability to repay, a borrower's source(s) of repayment, and when appropriate, compliance with the FICU's valuation policies at the time the modification is approved.

3. Providing borrowers with written disclosures that are accurate, clear and conspicuous and that are consistent with Federal and state consumer protection laws.

4. Appropriate reporting of loan status for modified loans in accordance with applicable law and accounting practices. The FICU shall not report a modified loan as past due if the loan was current prior to modification and the borrower is complying with the terms of the modification.

5. Prudent policies and procedures to help borrowers resume affordable and sustainable repayments that are appropriately structured, while at the same time minimizing losses to the credit union. The prudent policies and procedures must consider:

i. Whether the loan modifications are well-designed, consistently applied, and provide a favorable outcome for borrowers.

ii. The available options for borrowers to repay any missed payments at the end of their modifications to avoid delinquencies or other adverse consequences.

6. Appropriate safety and soundness safeguards to prevent the following:

i. Masking deteriorations in loan portfolio quality and understating charge-off levels; [5]

ii. Delaying loss recognition resulting in an understated allowance for loan and lease losses account or inaccurate loan valuations;

iii. Overstating net income and net worth (regulatory capital) levels; and

iv. Circumventing internal controls.

The credit union's risk management framework must include thresholds, based on aggregate volume of loan workout activity, that trigger enhanced reporting to the board of directors. This reporting will enable the credit union's board of directors to evaluate the effectiveness of the credit union's loan workout program, understand any implications to the organization's financial condition, and make any compensating adjustments to the overall business strategy. This information will also be available to examiners upon request.

To be effective, management information systems need to track the principal reductions and *charge-off* history of loans in workout programs by type of program. Any decision to re-age, extend, defer, renew, or rewrite a loan, like any other revision to contractual terms, must be supported by the credit union's management information systems. Sound management information systems identify and document any loan that is re-aged, extended, deferred, renewed, or rewritten, including the frequency and extent of such action. Documentation normally shows that credit union personnel communicated with the borrower, the borrower agreed to pay the loan in full under any new terms, and the borrower has the ability to repay the loan under any new terms.

---

[1] Terms defined in the Glossary will be italicized on their first use in the body of this =Appendix.

[2] For additional guidance on commercial and member business lending extension, deferral, renewal, and rewrite policies, see *Interagency Policy Statement on Prudent Commercial Real Estate Loan Workouts* (October 30, 2009) transmitted by Letter to Credit Unions No. 10–CU–07, and available at *http://www.ncua.gov.*

[3] Broad based credit union programs commonly used as a member benefit and implemented in a safe and sound manner limited to only accounts in good standing, such as Skip-a-Pay programs, are not intended to count toward these limits.

[4] In developing a written policy, the credit union board and management may wish to consider similar parameters as those established in the FFIEC's ''Uniform Retail Credit Classification and Account Management Policy'' (FFIEC Policy). 65 FR 36903 (June 12, 2000). The FFIEC Policy sets forth specific limitations on the number of times a loan can be re-aged (for open-end accounts) or extended, deferred, renewed or rewritten (for closed-end accounts). NCUA Letter to Credit Unions (LCU) 09–CU–19, ''Evaluating Residential Real Estate Mortgage Loan Modification Programs,'' also outlines policy best practices for real estate modifications. Those best practices remain applicable to real estate loan modifications (with the exception to the capitalization of credit union fees) but could be adapted in part by the credit union in their written loan workout policy for other loans.

[5] Refer to NCUA guidance on charge-offs set forth in LCU 03–CU–01, ''Loan Charge-off Guidance,'' dated January 2003. Examiners will require that a reasonable written charge-off policy is in place and that it is consistently applied. Additionally, credit unions need to adjust historical loss factors when calculating ALLL needs for pooled loans to account for any loans with protracted charge-off timeframes (for example, 12 months or more). See discussions on the latter point in the 2006 Interagency ALLL Policy Statement transmitted by Accounting Bulletin 06–1 (December 2006). Upon implementation of ASC 326—Financial Instruments—Credit Losses, credit unions will use the guidance in Interagency Policy Statement on Allowances for Credit Losses (May 2020).

Regulatory Reporting of Workout Loans Including TDR Past Due Status

Credit unions will calculate the past due status of all loans consistent with loan contract terms, including amendments made to loan terms through a formal restructure. Credit unions will report delinquency on the Call Report consistent with this policy.[6]

Loan Nonaccrual Policy

Credit unions must recognize interest income appropriately. Credit unions must place loans in nonaccrual status when doubt exists as to full collection of principal and interest or the loan has been in default for a period of 90 days or more. Upon placing a loan in nonaccrual, a credit union must reverse or charge-off previously accrued but uncollected interest. A nonaccrual loan may be returned to accrual status when a credit union expects repayment of the remaining contractual principal and interest or it is well secured and in process of collection.[7] This policy on loan accrual is consistent with longstanding credit union industry practice as implemented by the NCUA over the last several decades. The balance of the policy relates to *commercial* and *member business loan* workouts and is similar to the policies adopted by the federal banking agencies[8] as set forth in the FFIEC Call Report for banking institutions and its instructions.[9]

Nonaccrual Status

Credit unions may not accrue interest[10] on any loan where principal or interest has been in default for a period of 90 days or more unless the loan is both ''*well secured*'' and ''in the *process of collection*.''[11] For purposes of applying the ''well secured'' and ''in process of collection'' test for nonaccrual status listed above, the date on which a loan reaches nonaccrual status is determined by its contractual terms.

While a loan is in nonaccrual status, a credit union may treat some or all of the cash payments received as interest income on a cash basis provided no doubt exists about the collectability of the remaining *recorded investment in the loan.* A credit union must handle the reversal of previously accrued, but uncollected, interest applicable to any loan placed in nonaccrual status in accordance with GAAP.[12]

Restoration to Accrual Status for All Loans Except Commercial and Member Business Loan Workouts

A nonaccrual loan may be restored to accrual status when:

- Its past due status is less than 90 days and the credit union expects repayment of the remaining contractual principal and interest within a reasonable period;
- It otherwise becomes both *well secured* and *in the process of collection;* or
- The asset is a purchased impaired loan and it meets the criteria under GAAP for accrual of interest income under the accretable yield method. See ASC 310–30.

In restoring all loans to accrual status, if the credit union applied any interest payments received while the loan was in nonaccrual status to reduce the recorded investment in the loan, the credit union must not reverse the application of these payments to the loan's recorded investment (and must not credit interest income). Likewise, a credit union cannot restore the accrued but uncollected interest reversed or charged-off at the point the loan was placed on nonaccrual status to accrual; it can only be recognized as income if collected in cash or cash equivalents from themember.

Restoration to Accrual Status on Commercial and Member Business Loan Workouts[13]

A formally restructured commercial or member business loan workout need not be maintained in nonaccrual status, provided the restructuring and any charge-off taken on the loan are supported by a current, well-documented credit evaluation of the borrower's financial condition and prospects for repayment under the revised terms. Otherwise, the restructured loan must remain in nonaccrual status.

The credit union's evaluation must include consideration of the borrower's sustained historical repayment performance for a reasonable period prior to the date on which the loan is returned to accrual status. A sustained period of repayment performance is a minimum of six consecutive payments, and includes timely payments under the restructured loan's terms of principal and interest in cash or cash equivalents. In returning the commercial or member business workout loan to accrual status, a credit union may consider sustained historical repayment performance for a reasonable time prior to the restructuring. Such a restructuring must improve the collectability of the loan in accordance with a reasonable repayment schedule and does not relieve the credit union from the responsibility to promptly charge off all identified losses.

The following graph provides an example of a schedule of repayment performance to demonstrate a determination of six consecutive payments. If the original loan terms required a monthly payment of $1,500, and the credit union lowered the borrower's payment to $1,000 through formal commercial or member business loan restructure, then based on the first row of the graph, the ''*sustained historical repayment performance for a reasonable time prior to the restructuring*'' would encompass five of the pre-workout consecutive payments that were at least $1,000 (months 1 through 5). In total, the six consecutive repayment burden would be met by the first month post workout (month 6).

In the second row, only one of the pre-workout payments would count toward the six consecutive repayment requirement (month 5), because it is the first month in which the borrower made a payment of at least $1,000 after failing to pay at least that amount. Therefore, the loan would remain on nonaccrual for at least five post-workout consecutive payments (months 6 through 10) provided the borrower continues to make payments consistent with the restructured terms.

[6] Subsequent Call Reports and accompanying instructions will reflect this policy, including focusing data collection on loans meeting the definition of TDR under GAAP. In reporting TDRs on regulatory reports, the data collections will include all TDRs that meet the GAAP criteria for TDR reporting, without the application of materiality threshold exclusions based on scoping or reporting policy elections of credit union preparers or their auditors. Credit unions should also refer to ASC Subtopic 310–40 when determining if a restructuring of a debt constitutes a TDR.

[7] Placing a loan in nonaccrual status does not change the loan agreement or the obligations between the borrower and the credit union. Only the parties can effect a restructuring of the original loan terms or otherwise settle the debt.

[8] The federal banking agencies are the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of the Comptroller of the Currency.

[9] FFIEC Report of Condition and Income Forms, Instructions and Supplemental Instructions, *https://www.ffiec.gov/forms041.htm.*

[10] Nonaccrual of interest also includes the amortization of deferred net loan fees or costs, or the accretion of discount. Nonaccrual of interest on loans past due 90 days or more is a longstanding agency policy and credit union practice.

[11] A purchased credit impaired loan asset need not be placed in nonaccrual status as long as the criteria for accrual of income under the interest method in GAAP is met. Also, the accrual of interest on workout loans is covered in a later section of this appendix.

[12] Acceptable accounting treatment includes a reversal of all previously accrued, but uncollected, interest applicable to loans placed in a nonaccrual status against appropriate income and balance sheet accounts. For example, one acceptable method of accounting for such uncollected interest on a loan placed in nonaccrual status is:

(1) To reverse all of the unpaid interest by crediting the ''accrued interest receivable'' account on the balance sheet,

(2) to reverse the uncollected interest that has been accrued during the calendar year-to-date by debiting the appropriate ''interest and fee income on loans'' account on the income statement, and

(3) to reverse any uncollected interest that had been accrued during previous calendar years by debiting the ''allowance for loan and lease losses'' account on the balance sheet.

The use of this method presumes that credit union management's additions to the allowance through charges to the ''provision for loan and lease losses'' on the income statement have been based on an evaluation of the collectability of the loan and lease portfolios and the ''accrued interest receivable'' account.

[13] This policy is derived from the ''Interagency Policy Statement on Prudent Commercial Real Estate Loan Workouts'' the NCUA and the other financial regulators issued on October 30, 2009.

Pre-workout					Post-workout				
Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10
$1,500 1,500	$1,200 1,200	$1,200 900	$1,000 875	$1,000 1,000	$1,000 1,000	$1,000 1,000	$1,000 1,000	$1,000 1,000	$1,000 1,000

After a formal restructure of a commercial or member business loan, if the restructured loan has been returned to accrual status, the loan otherwise remains subject to the nonaccrual standards of this policy. If any interest payments received while the commercial or member business loan was in nonaccrual status were applied to reduce the recorded investment in the loan the application of these payments to the loan's recorded investment must not be reversed (and interest income must not be credited). Likewise, accrued but uncollected interest reversed or charged-off at the point the commercial or member business workout loan was placed on nonaccrual status cannot be restored to accrual; it can only be recognized as income if collected in cash or cash equivalents from the member.

The following tables summarize nonaccrual and restoration to accrual requirements previously discussed:

TABLE 1—NONACCRUAL CRITERIA

Action	Condition identified	Additional consideration
Nonaccrual on All Loans	90 days or more past due unless loan is both well-secured and in the process of collection; or The loan is maintained on the Cash basis because there is a deterioration in the financial condition of the borrower, or for which payment in full of principal or interest is not expected	See Glossary definitions for ''well secured'' and ''in the process of collection.''
Nonaccrual on Commercial or Member Business Loan Workouts.	Continue on nonaccrual at workout point and until restore to accrual criteria are met.	See Table 2—Restore to Accrual.

TABLE 2—RESTORE TO ACCRUAL

Action	Condition identified	Additional consideration
Restore to Accrual on All Loans except Commercial or Member Business Loan Workouts.	When a loan is less than 90 days past due and the credit union expects repayment of the remaining contractual principal and interest within a reasonable period, or. When it otherwise becomes both ''well secured'' and ''in the process of collection''; or The asset is a purchased impaired loan and it meets the criteria under GAAP (see ASC 310–30) for accrual of interest income under the accretable yield method.	See Glossary definitions for ''well secured'' and ''in the process of collection.'' Interest payments received while the loan was in nonaccrual status and applied to reduce the recorded investment in the loan must not be reversed and income credited. Likewise, accrued but uncollected interest reversed or charged-off at the point the loan was placed on nonaccrual status cannot be restored to accrual.
Restore to Accrual on Commercial or Member Business Loan Workouts.	Formal restructure with a current, well documented credit evaluation of the borrower's financial condition and prospects for repayment under the revised terms.	The evaluation must include consideration of the borrower's sustained historical repayment performance for a minimum of six timely consecutive payments comprised of principal and interest. In returning a loan to accrual status, a credit union may take into account sustained historical repayment performance for a reasonable time prior to the restructured terms. Interest payments received while the commercial or member business loan was in nonaccrual status and applied to reduce the recorded investment in the loan must not be reversed and income credited. Accrued but uncollected interest reversed or charged-off at the point the commercial or member business loan was placed on nonaccrual status cannot be restored to accrual.

Glossary [14]

''*Capitalization of Interest*'' constitutes the addition of accrued but unpaid interest to the principal balance of a loan.

''*Cash Basis*'' method of income recognition is set forth in GAAP and means while a loan is in nonaccrual status, some or all of the cash interest payments received may be treated as interest income on a cash basis provided no doubt exists about the collectability of the remaining recorded investment in the loan.[15]

[14] Terms defined in the Glossary will be italicized on their first use in the body of this guidance.

[15] Acceptable accounting practices include: (1) Allocating contractual interest payments among interest income, reduction of the recorded investment in the asset, and recovery of prior charge-offs. If this method is used, the amount of income that is recognized would be equal to that which would have been accrued on the loan's remaining recorded investment at the contractual rate; and, (2) accounting for the contractual interest in its entirety either as income, reduction of the recorded investment in the asset, or recovery of

''*Charge-off*'' means a direct reduction (credit) to the carrying amount of a loan carried at amortized cost resulting from uncollectability with a corresponding reduction (debit) of the ALLL. Recoveries of loans previously charged off must be recorded when received.

''*Commercial Loan*'' is defined consistent with Section 723.2 of the NCUA's MEMBER BUSINESS LOANS; COMMERCIAL LENDING Rule, 12 CFR 723.2.

''*Generally accepted accounting principles (GAAP)*'' means official pronouncements of the FASB as memorialized in the FASB Accounting Standards Codification® as the source of authoritative principles and standards recognized to be applied in the preparation of financial statements by federally insured credit unions in the United States with assets of $10 million or more.

''*In the process of collection*'' means collection of the loan is proceeding in due course either: (1) Through legal action, including judgment enforcement procedures, or (2) in appropriate circumstances, through collection efforts not involving legal action which are reasonably expected to result in repayment of the debt or in its restoration to a current status in the near future, *i.e.,* generally within the next 90 days.

''*Member Business Loan*'' is defined consistent with Section 723.8 of the NCUA's MEMBER BUSINESS LOANS; COMMERCIAL LENDING Rule, 12 CFR 723.8.

''*New Loan*'' means the terms of the revised loan are at least as favorable to the credit union (*i.e.,* terms are market-based, and profit driven) as the terms for comparable loans to other customers with similar collection risks who are not refinancing or restructuring a loan with the credit union, and the revisions to the original debt are more than minor.

''*Past Due*'' means a loan is determined to be delinquent in relation to its contractual repayment terms including formal restructures, and must consider the time value of money. Credit unions may use the following method to recognize partial payments on ''consumer credit,'' *i.e.,* credit extended to individuals for household, family, and other personal expenditures, including credit cards, and loans to individuals secured by their personal residence, including home equity and home improvement loans. A payment equivalent to 90 percent or more of the contractual payment may be considered a full payment in computing past due status.

''*Recorded Investment in a Loan*'' means the loan balance adjusted for any unamortized premium or discount and unamortized loan fees or costs, less any amount previously charged off, plus recorded accrued interest.

''*Troubled Debt Restructuring*'' is as defined in GAAP and means a restructuring in which a credit union, for economic or legal reasons related to a member borrower's financial difficulties, grants a concession to the borrower that it would not otherwise consider.[16] The restructuring of a loan may include, but is not necessarily limited to:

(1) The transfer from the borrower to the credit union of real estate, receivables from third parties, other assets, or an equity interest in the borrower in full or partial satisfaction of the loan,

(2) a modification of the loan terms, such as a reduction of the stated interest rate, principal, or accrued interest or an extension of the maturity date at a stated interest rate lower than the current market rate for new debt with similar risk, or

(3) a combination of the above.

A loan extended or renewed at a stated interest rate equal to the current market interest rate for new debt with similar risk is not to be reported as a restructured troubled loan.

''*Well secured*'' means the loan is collateralized by: (1) A perfected security interest in, or pledges of, real or personal property, including securities with an estimable value, less cost to sell, sufficient to recover the recorded investment in the loan, as well as a reasonable return on that amount, or (2) by the guarantee of a financially responsible party.

''*Workout Loan*'' means a loan to a borrower in financial difficulty that has been formally restructured so as to be reasonably assured of repayment (of principal and interest) and of performance according to its restructured terms. A workout loan typically involves a *re-aging, extension, deferral, renewal, or rewrite* of a loan.[17] For purposes of this policy statement, workouts do not include loans made to market rates and terms such as refinances, borrower retention actions, or new loans.[18]

''*Extension*'' means extending monthly payments on a closed-end loan and rolling back the maturity by the number of months extended. The account is shown current upon granting the extension. If extension fees are assessed, they must be collected at the time of the extension and not added to the balance of the loan.

''*Deferral*'' means deferring a contractually due payment on a closed-end loan without affecting the other terms, including maturity, of the loan. The account is shown current upon granting the deferral.

''*Renewal*'' means underwriting a matured, closed-end loan generally at its outstanding principal amount and on similar terms.

''*Rewrite*'' means significantly changing the terms of an existing loan, including payment amounts, interest rates, amortization schedules, or its final maturity.

[FR Doc. 2020–25988 Filed 12–3–20; 8:45 am]

BILLING CODE 7535–01–P

prior charge-offs, depending on the condition of the asset, consistent with its accounting policies for other financial reporting purposes.

[16] FASB ASC 310–40, ''Troubled Debt Restructuring by Creditors.''

[17] ''*Re-Age*'' means returning a past due account to current status without collecting the total amount of principal, interest, and fees that are contractually due.

[18] There may be instances where a workout loan is not a TDR even though the borrower is experiencing financial hardship. For example, a workout loan would not be a TDR if the fair value of cash or other assets accepted by a credit union from a borrower in full satisfaction of its receivable is at least equal to the credit union's recorded investment in the loan, *e.g.,* due to charge-offs.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1107; Project Identifier 2019–SW–049–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus 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 all Airbus Helicopters Model SA330J helicopters. This proposed AD was prompted by a report of failure of a second stage planet gear of the main gear box (MGB). This proposed AD would require replacement of the MGB particle detector assembly with an improved, elongated MGB particle detector assembly, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. 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 January 19, 2021.

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 material that will be incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet: *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA,

call 817–222–5110. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1107.

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–2020–1107; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Mahmood G. Shah, Aviation Safety Engineer, Fort Worth ACO Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: 817–222–5538; email: *mahmood.g.shah@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 **ADDRESSES**. Include ''Docket No. FAA–2020–1107; Project Identifier 2019–SW–049–AD'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) 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 agency will also post a report summarizing each substantive verbal contact received about this proposal.

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 Mahmood G. Shah, Aviation Safety Engineer, Fort Worth ACO Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: 817–222–5538; email: *mahmood.g.shah@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0108, dated May 17, 2019 (EASA AD 2019–0108) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus Helicopters Model SA330J helicopters.

This proposed AD was prompted by a report of failure of a second stage planet gear of the MGB on a Model EC225 helicopter. Following a review of design similarities, it was determined that such an event might also occur on Model SA330J helicopters. The FAA is proposing this AD to address failure of a second stage planet gear of the MGB, which could lead to loss of control of the helicopter. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2019–0108 describes procedures for replacement of the MGB particle detector assembly with an improved, elongated MGB particle detector assembly.

This material 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 This 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 bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA 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 EASA AD 2019–0108, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2019–0108 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2019–0108 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in the EASA AD. Service information specified in EASA AD 2019–0108 that is required for compliance with EASA AD 2019–0108 will be available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1107 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 15 helicopters of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
4 work-hours × $85 per hour = $340	$6,795	$7,135	$107,025

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:

Airbus Helicopters: Docket No. FAA–2020–1107; Project Identifier 2019–SW–049–AD.

(a) Comments Due Date

The FAA must receive comments by January 19, 2021.

(b) Affected Airworthiness Directives (ADs)

None.

(c) Applicability

This AD applies to all Airbus Helicopters Model SA330J helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 6320, Main rotor gearbox.

(e) Reason

This AD was prompted by a report of failure of a second stage planet gear of the main gear box (MGB). The FAA is issuing this AD to address failure of a second stage planet gear of the MGB, which could lead to loss of control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2019–0108, dated May 17, 2019 (EASA AD 2019–0108).

(h) Exceptions to EASA AD 2019–0108

(1) Where EASA AD 2019–0108 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2019–0108 does not apply to this AD.

(3) Where EASA AD 2019–0108 refers to flight hours (FH), this AD requires using hours time-in-service.

(4) Although the service information referenced in EASA 2019–0108 specifies to discard certain parts, this AD does not include that requirement.

(i) Special Flight Permit

Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the helicopter can be modified (if the operator elects to do so), provided that no passengers are onboard.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Manager, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: 817–222–5110; email: *9-ASW-FTW-AMOC-Requests@faa.gov.*

(k) Related Information

(1) For EASA AD 2019–0108, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* internet: *www.easa.europa.eu*. You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu*. You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1107.

(2) For more information about this AD, contact Mahmood G. Shah, Aviation Safety Engineer, Fort Worth ACO Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: 817–222–5538; email: *mahmood.g.shah@faa.gov.*

Issued on November 30, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–26672 Filed 12–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1106; Project Identifier MCAI–2020–01065–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS 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 certain Airbus SAS Model A350–941 and A350–1041 airplanes. This proposed AD was prompted by reports that suitable corrosion protection treatment had not been applied to certain areas of the seat track. This proposed AD would require a one-time detailed inspection of the seat tracks between certain frames for suitable corrosion protection or presence of corrosion, and on-condition actions if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which will be incorporated by reference. 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 January 19, 2021.

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 material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1106.

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–2020–1106; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218; email *kathleen.arrigotti@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–2020–1106; Project Identifier MCAI–2020–01065–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) 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 agency will also post a report summarizing each substantive verbal contact received about this proposed AD.

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 Kathleen Arrigotti, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218; email *kathleen.arrigotti@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0166, dated July 27, 2020 (EASA AD 2020–0166) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Airbus SAS Model A350–941 and A350–1041 airplanes.

This proposed AD was prompted by reports that suitable corrosion protection treatment had not been applied to certain areas of the seat track. The FAA is proposing this AD to address a potential structural deficiency at certain seat track locations, providing insufficient resistance to environmental damage. This condition, if not addressed, could lead to seat or monument detachment during an emergency landing, possibly resulting in injury to occupants and preventing safe evacuation from the airplane. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0166 describes procedures for a one-time detailed inspection of the seat tracks between certain frames for suitable corrosion protection or presence of corrosion, and on-condition actions if necessary. On-condition actions include applying protection, removing corrosion, measuring the dimensions of the seat rails, and performing a splice repair.

This material 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 This 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 the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA

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 EASA AD 2020–0166 described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2020–0166 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2020–0166 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in the EASA AD. Service information specified in EASA AD 2020–0166 that is required for compliance with EASA AD 2020–0166 will be available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1106 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 5 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
14 work-hours × $85 per hour = $1,190	$0	$1,190	$5,950

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
6 work-hours × $85 per hour = $510	$0	$510

According to the manufacturer, some or all 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 for affected individuals. As a result, the FAA has included all known costs in the 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 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):

Airbus SAS: Docket No. FAA–2020–1106; Project Identifier MCAI–2020–01065–T.

(a) Comments Due Date

The FAA must receive comments by January 19, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A350–941 and A350–1041 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2020–0166, dated July 27, 2020 (EASA AD 2020–0166).

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by reports that suitable corrosion protection treatment had not been applied to certain areas of the seat track. The FAA is issuing this AD to address a potential structural deficiency at certain seat track locations, providing insufficient resistance to environmental damage. This condition, if not addressed, could lead to seat or monument detachment during an emergency landing, possibly resulting in injury to occupants and preventing safe evacuation from the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2020–0166.

(h) Exceptions to EASA AD 2020–0166

(1) Where EASA AD 2020–0166 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2020–0166 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2020–0166 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation 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 responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC)*: For any service information referenced in EASA AD 2020–0166 that contains RC procedures and tests: Except as required by paragraph (j)(2) of this AD, RC procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) For information about EASA AD 2020–0166, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1106.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218; email *kathleen.arrigotti@faa.gov.*

Issued on November 30, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–26684 Filed 12–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–469]

RIN 1117–AB45

Partial Filling of Prescriptions for Schedule II Controlled Substances

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 became law. One provision of the Comprehensive Addiction and Recovery Act of 2016 amended the Controlled Substances Act to allow for the partial filling of prescriptions for schedule II controlled substances under certain conditions. The Drug Enforcement Administration is hereby proposing to amend its regulations to conform to this new statutory provision and to set forth the corresponding regulatory requirements.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before February 2, 2021. 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.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before February 2, 2021.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–469'' on all correspondence, including any attachments.

DEA encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions to submit comments. Upon submission of your comment, you will receive a Comment Tracking Number. 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 that duplicate an electronic submission 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: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB45/Docket No. DEA–469.

FOR FURTHER INFORMATION CONTACT:

Scott A. Brinks, Regulatory Drafting and Policy 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 the personal identifying information you do not want to be 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 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 or personal identifying 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) or confidential business information included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Background and Statutory Authority

On July 22, 2016, the President signed the Comprehensive Addiction and Recovery Act (CARA) of 2016 into law as Public Law 114–198. One of the provisions of the CARA amended the Controlled Substances Act (CSA) to allow for the partial filling of prescriptions for schedule II controlled substances under certain conditions. Specifically, the CARA amended 21 U.S.C. 829 by adding new subsection (f), which allows a pharmacist to partially fill a prescription for a schedule II controlled substance where requested by the prescribing practitioner or the patient. Subsection (f) further provides that for such partial filling to be lawful under the CSA, all of the following conditions must be satisfied: (1) The partial filling must not be prohibited by State law; (2) the prescription must be written and filled in accordance with the CSA, DEA regulations, and State law; and (3) the total quantity dispensed in all partial fillings must not exceed the total quantity prescribed. In addition, subsection (f) provides that the remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, must be filled no later than 30 days after the date on which the prescription is written, unless the prescription is issued as an emergency oral prescription, in which case the remaining portion, if filled, must be filled no later than 72 hours after it was issued.

This proposed rule would revise DEA regulations to incorporate the foregoing new statutory provisions. In addition, DEA is proposing to further revise its regulations to address certain regulatory requirements not addressed by the CARA. In particular, the CARA does not address how the prescribing practitioner should indicate that a prescription for a schedule II controlled substance must be partially filled. Likewise, the CARA does not specify how a pharmacist should record the partial filling of such a prescription. The CARA provides that partial filling of schedule II prescriptions is permitted if the prescription is written and filled in accordance with, among other things, regulations issued by DEA. 21 U.S.C. 829(f)(1)(B). Accordingly, Congress gave DEA explicit authorization to fill in any gaps in the regulatory scheme not addressed by Congress itself in the CARA. DEA is exercising this authority by issuing this proposed rule, which is intended to give practitioners and pharmacists clear guidance in this area, and to allow for proper auditing by DEA.

In addition, there is potential for benefit to patients and society as a result of this proposed rule. For patients, partial filling could lower the cost of prescriptions by reducing the quantity of unused schedule II controlled substances due to not needing to continue on drug therapy. For instance, a patient would not have to pay for filling an entire prescription when only a portion of the prescription is filled because there is a likelihood that the patient may not need to consume the maximum number of dosage units prescribed. Similarly, the patient's insurance company or other program paying for or subsidizing the cost of the patient's drugs (*e.g.,* a pharmacy's co-pay plan or a government program such as Medicare or Medicaid), would avoid such unnecessary expense. Reducing the dispensing of schedule II drugs that are ultimately not needed would also help to ameliorate the danger that the patient might become dependent upon or addicted to dangerous opioids or other schedule II drugs. The existence of unused drugs in U.S. households contributes to growing rates of prescription drug abuse among Americans. Keeping and storing unused medications in households pose several dangers related to diversion, accidental overdose, and consumption of spoiled substances.[1] Reducing the quantity of unused schedule II controlled substances would reduce the risk of diversion.

There are a number of reasons unused drugs remain in U.S. households. For example, in one survey of 139 respondents, patients cited the following: condition resolved/symptoms improved (42.4 percent); did not believe I needed to take it (12.9 percent); did not feel it was helping the condition (7.1 percent); experienced side effects (6.5 percent); forgot or did not get around to taking it (5.8 percent); person on medications no longer lives there (5.0

[1] ''Safe Disposal of Unused Controlled Substances: Current Challenges and Opportunities for Reform,'' Avalere, *http://www.ncdoi.com/osfm/safekids/documents/omd/safedisposalofunusedcontrolledsubstancesreport.pdf.*

percent); physician asked to stop it (4.3 percent); or other reason (15.8 percent).[2]

In recent years, a number of states have enacted laws placing limits on certain controlled substances that may be prescribed. DEA has received inquiries from pharmacists and others asking whether it is permissible under Federal law to fill a schedule II prescription that is otherwise valid, but which exceeds the quantitative limit under State law. The CARA provides that partial filling of schedule II prescriptions is permitted if the prescription is written and filled in accordance with, among other things, State law. 21 U.S.C. 829(f)(1)(B). DEA interprets a prescription written for a quantity that exceeds the limits of State law to be invalid, and therefore, the prescription may not be filled as written. Because such a prescription is invalid, it also cannot be partially filled as a means of getting around the limits imposed by State law.

Partial Fill Request by Practitioner

How a Practitioner May Request That a Prescription Be Partially Filled Under the Proposed Rule

The proposed rule states that where a practitioner issues a prescription for a schedule II controlled substance and wants the prescription to be partially filled (as the CARA now allows), the practitioner must specify the quantity to be dispensed in the partial filling on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record. This information would need to be included on the prescription, along with other information required for issuing a prescription under 21 CFR 1306.05, at the time it is signed by the practitioner, and in the case of an emergency oral prescription, when communicated by the prescribing practitioner to the pharmacist. DEA proposes this approach to ensure that the practitioner's intent regarding partial filling is made clear to the pharmacist, and will be properly memorialized in the dispensing records.

How a Pharmacy Would Be Required To Record the Partial Filling of a Prescription for a Schedule II Controlled Substance When Requested By the Prescribing Practitioner

When presented with a prescription on which the prescribing practitioner has properly specified his/her intent that the prescription for a schedule II controlled substance be partially filled, the proposed rule would require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations for other circumstances.[3] Specifically, upon each such partial filling requested by a prescribing practitioner, the dispensing pharmacist must make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record (as is currently required under 21 CFR 1306.13(a) when the pharmacist is unable to supply the full quantity called for in the prescription). For electronic prescriptions, there must be an electronic prescription record, and the record must be permanently attached to the electronic prescription. Also, for each such partial filling, the pharmacy must maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions specifically, pharmacy applications must allow required information pertaining to the quantity, date, and the dispenser to be linked to each electronic controlled substance prescription record (as currently required by 21 CFR 1311.205(b)(10)).

Partial Fill Request by Patient

How a Patient May Request the Partial Filling of a Schedule II Prescription

As a result of the CARA, 21 U.S.C. 829(f) now provides that a prescription for a schedule II controlled substance may be partially filled at the request of either the prescriber or the patient. Thus, even if the prescribing practitioner does not specify on the prescription his/her intent that the prescription be partially filled, the patient may make such request to the pharmacy. The CARA does not place any limitations on how the patient may make a partial fill request. In addition, DEA recognizes that many post-surgery patients may have a difficult time visiting pharmacy in person. Therefore, this proposed rule would not require an in-person request by the patient in every case and would allow alternative pathways for the patient to make such a request and specify the amount to be filled (*e.g.,* phone call by the patient to the pharmacist, or a signed written note from the patient and delivered by a family member to the pharmacist).

However, it should be noted that the CARA only authorizes the ''patient''—not a member of the patient's household—to make such request. Whereas the CSA defines ''ultimate user'' to include a member of the patient's household (21 U.S.C. 802(27)), the new section 829(f) refers only to ''the patient or the practitioner that wrote the prescription'' making the request for the partial fill. Thus, the CARA did not authorize members of the patient's household to request the partial filling of a prescription on behalf of the patient.

How a Pharmacy Must Record the Partial Filling of a Prescription for a Schedule II Controlled Substance When Requested By the Patient

Under the proposed rule, when partially filling a prescription for a schedule II controlled substance at the request of the patient, the pharmacist must make the same notation on the prescription as when partially filling a prescription at the request of the prescribing practitioner. With an electronic prescription, as discussed above in the section on pharmacy recording requirements, the notation must be linked to an electronic prescription record. Since the prescription will not contain the partial fill instructions from the prescriber, the pharmacy would also be required under the proposed rule to indicate on the prescription that the patient requested the partial fill. For uniformity and clarity, DEA is proposing that the pharmacy record on all such prescriptions: (1) ''patient requested partial fill on [date such request was made],'' and (2) the quantity dispensed. In the event the prescribing practitioner already made the request to partially fill the prescription t, the pharmacy will not be required to make any notation on the prescription indicating that the patient requested a partial fill, unless the patient requested a smaller amount. However, where a practitioner has requested the partial filling of a prescription, the patient may not request a partial filling in an amount greater than that specified by the practitioner.

Request for Public Comment

Parts of this proposed rule merely restate the provisions of the CARA setting forth the general requirements

[2] ''Taking Stock of Medication Wastage: Unused Medications in U.S. Households.'' NeuroImage, Academic Press, 16 Oct. 2014. *www.sciencedirect.com/science/article/pii/S1551741114003337?via%3Dihub.*

[3] Longstanding DEA regulations, which would not be changed by this proposed rule, also allow the partial filling of a schedule II prescription where the pharmacist is unable to supply the full quantity called for in the prescription (§ 1306.13(a)) and for a patient in a long-term care facility or with a terminal illness (§ 1306.13(b) and (c)).

for partial filling of prescriptions for schedule II controlled substances. Since these provisions are mandated by Congress, DEA is obligated to incorporate them into the agency regulations. However, other parts of the proposed rule would fill in any gaps in the regulatory scheme not addressed by Congress. Accordingly, DEA solicits public comment on the following provisions of the proposed rule: § 1306.13(b)(3), (4), and (5).

Regulatory Analysis

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, Reducing Regulation, and Controlling Regulatory Costs

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, public health and safety, and environmental advantages; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. The E.O. classifies a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

DEA expects that this proposed rule will have an annual effect on the economy of $100 million or more in cost savings and therefore is an economically significant regulatory action. The analysis of benefits and costs is below.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined and it has been determined to be a significant regulatory action under E.O. 12866, and therefore has been submitted to the Office of Management and Budget (OMB) for review.

I. Need for the Rule

As discussed above, the CARA was signed into law on July 22, 2016. One of the provisions of the CARA amended the CSA to allow for the partial filling of prescriptions for schedule II controlled substances under certain conditions, providing flexibilities to prescribers and patients. Specifically, the CARA amended 21 U.S.C. 829 by adding new subsection (f), which allows a pharmacist to partially fill a prescription for a schedule II controlled substance where requested by the prescribing practitioner or the patient. Subsection (f) further provides that for such partial filling to be lawful under the CSA, all of the following conditions must be satisfied: (1) The partial filling must not be prohibited by State law; (2) the prescription must be written and filled in accordance with the CSA, DEA regulations, and State law; and (3) the total quantity dispensed in all partial fillings must not exceed the total quantity prescribed. In addition, subsection (f) provides that the remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, must be filled no later than 30 days after the date on which the prescription is written, unless the prescription is issued as an emergency oral prescription, in which case the remaining portions, if filled, must be filled no later than 72 hours after it was issued.

II. Alternative Approaches

When the prescriber requests the partial fill, the pharmacy's actions are straightforward. The pharmacist dispenses the prescription according to the prescriber's partial fill instructions and makes the required notations on the prescription, and the pharmacy maintains the required dispensing records. However, DEA considered three regulatory alternatives regarding the required notifications when the partial fill is at the request of the patient. DEA considered whether the pharmacist should (1) notify the prescribing practitioner or the prescribing practitioner's agent of the patient's request to partially fill the prescription, and obtain the prescribing practitioner's consent for the quantity; (2) notify the prescribing practitioner or the prescribing practitioner's agent of the patient's partial fill request, but not require the prescribing practitioner's consent; or (3) simply dispense the partial fill as requested without any notification or consent. As the pharmacist's requirement for notification or consent is the only difference between the alternatives, the alternatives analysis below only examines the estimated cost of notification or consent. A complete discussion of benefits and costs is described in the following section.

Alternative 1: Obtain Prescribing Practitioner's Consent for the Partial Fill Quantity Prior to Dispensing

The first alternative would require the prescribing practitioner's consent of the quantity to be dispensed before the pharmacist dispenses a partial fill at the patient's request. Upon receiving a patient's request for a partial fill, the pharmacist would contact the prescribing practitioner or the prescribing practitioner's agent, and confirm that the prescribing practitioner concurs with the requested partial fill quantity. After confirmation, the pharmacist would dispense the partial fill and make the required notation on the prescription. The notation includes the method of notification (*e.g.,* telephone, email, voicemail) and the person notified.

DEA estimates obtaining consent would require six minutes from each of the parties involved: The pharmacist to request consent, the prescribing office to review request and for the prescribing practitioner or practitioner's agent to give consent, and the patient to wait while consent is received. To estimate the cost, DEA used the following labor wage and employment cost rates from the U.S. Department of Labor, Bureau of Labor Statistics (BLS). The following occupations' median hourly wages were noted: [4]

- *Pharmacist requesting consent:* 29–1051 Pharmacists, $60.64.
- *Prescriber's representative to give consent:* 43–6033 Medical Secretaries, $17.19.
- *Patient:* 00–0000 All Occupations, $18.54.

Additionally, a load of 42.7 percent for benefits was applied to the median hourly wages to obtain loaded median hourly wages below: [5]

- *Pharmacist requesting consent:* 29–1051 Pharmacists, $86.53.
- *Prescriber's representative to give consent:* 43–6033 Medical Secretaries, $24.53.

[4] BLS, May 2018 National Occupational Employment and Wage Estimates, United States. *https://www.bls.gov/oes/current/oes_nat.htm.* (Accessed 2/6/2020.)

[5] BLS, ''Employer Costs for Employee Compensation—September 2019'' (ECEC) reports that average benefits for private industry is 29.9 percent of total compensation. The 29.9 percent of total compensation equates to 42.7 percent (29.9%/70.1%) load on wages and salaries.

• *Patient:* 00–0000 All Occupations, $26.51.

Therefore, the estimated cost of obtaining consent (six minutes per occurrence) would cost the pharmacy $8.65, the prescriber $2.45, and the patient $2.65, for a total $13.85 per occurrence.

While DEA does not have a strong basis to estimate the number of instances the patient will request partial filling of a prescription for schedule II control substance, in the Cost Savings discussion below, the estimated total prescriptions for potential partial filling is 36,375,279. DEA used the midpoint between 0 and 100 percent—half (18,187,640)—to estimate the cost savings. DEA does not know all the reasons a patient may request a partial fill, but believes a patient requesting a partial filling of a prescription for a schedule II controlled substance may seek a partial fill because: The patient is aware of the potential dangers of excess opioids in the household, the patient does not want excess opioids in the household, the patient believes he or she will not need all the dosages prescribed, and there is no additional cost or logistical burden as a result of the partial fill. DEA further believes that patients are likely to follow the instructions of prescribers, and estimates only a small minority of the estimated 18,187,640 requests for partial fills will be at the request of the patient. For the purposes of this analysis, DEA assumes 10 percent, or 1,818,764 partial fills will be at the request of the patient. Applying the cost per occurrence to the number of occurrences, this alternative is estimated to cost pharmacies approximately $15.7 million per year for the pharmacists to obtain consent, prescribing practitioners approximately $4.5 million per year to give consent, and patients $4.8 million while waiting for the pharmacist to obtain consent from the prescribing practitioner or practitioner's agent for a total $25.0 million per year. The table below summarizes this calculation.

TABLE 1—SUMMARY CALCULATION FOR ALTERNATIVE 1

	Loaded hourly wage ($)	Time required (hours)	Cost per occurrence ($)	Number of occurrences	Total cost ($M)
Pharmacy	86.53	0.1	8.65	1,818,764	15.7
Prescriber	24.53	0.1	2.45	1,818,764	4.5
Patient	26.51	0.1	2.65	1,818,764	4.8
Total	N/A	N/A	13.75	N/A	25.0

This alternative was not selected. It is contrary to the plain language of the statutory text which allows a patient to request a partial fill without obtaining the practitioner's consent. Although this alternative ensures consideration of the partial fill by the prescribing practitioner, DEA believes this alternative is unnecessarily burdensome. While DEA does not have a basis to estimate the likelihood of the prescribing practitioner denying consent for partial fills, DEA assumes denials would be rare. DEA welcomes public comments regarding this assumption. The patient may request a partial fill for a variety of reasons, and a partial fill request does not necessarily mean that the remaining portions of the prescription will not be filled. While making the prescribing practitioner aware of the partial fill would be helpful, requiring consent prior to the pharmacist's dispensing the partial fill would be unnecessarily burdensome, and, thus, this alternative was not selected.

Alternative 2: Notify the Prescribing Practitioner of the Partial Fill Quantity After Dispensing

The second alternative would require notification to the prescribing practitioner or the prescribing practitioner's agent of the quantity dispensed upon the patient's request for the partial fill. In this scenario, the prescribing practitioner's consent for the partial fill would not be required. Instead, the pharmacist would partially fill the prescription based on the patient's request, notify the prescribing practitioner or the prescribing practitioner's agent of the quantity dispensed, and make the required notation on the prescription. The notation is the same method as for alternative 1.

DEA estimates notifying the prescribing practitioner will require three minutes from each of the parties involved: The pharmacist to contact the prescribing office to give notice and the prescribing office to receive and review notice. Using the same BLS occupations and loaded median hourly wages as Alternative 1, the estimated cost of each notification (three minutes per occurrence) would cost the pharmacy $4.33 and the prescriber $1.23 for a total $5.56 per occurrence.

Applying the same estimate of 1,818,764 partial fills, as in Alternative 1, this alternative is estimated to cost pharmacies approximately $7.9 million per year for the pharmacists to give notice and prescribing practitioners approximately $2.2 million per year to receive and review notice. The table below summarizes this calculation.

TABLE 2—SUMMARY CALCULATION FOR ALTERNATIVE 2

	Loaded hourly wage ($)	Time required (hours)	Cost per occurrence ($)	Number of occurrences	Total cost ($M)
Pharmacy	86.53	0.05	4.33	1,818,764	7.9
Prescriber	24.53	0.05	1.23	1,818,764	2.2
Total	N/A	N/A	5.56	N/A	10.1

This alternative was not selected. DEA believes that this alternative is also unnecessarily burdensome. Although this alternative would ensure that the prescribing practitioner is made aware of the partial filling of the prescription and could react to this information if needed. However, it would cause an additional compliance-burden on both the pharmacy and prescribing practitioner.

Alternative 3: Dispense Partial Fill as Requested Without Consent of, or Notification to, the Prescribing Practitioner

The third alternative would not require the consent of, or notification to, the prescribing practitioner described in alternative 1 or 2, respectively. In this alternative, the pharmacist would partially fill the prescription based on the patient's request and make the required notation on the prescription. This alternative results in no notification-related cost to the pharmacy or prescriber.

This alternative was selected. Although a partial fill at the request of the patient may represent a departure from the prescribing practitioner's dispensing instructions, this alternative is the least burdensome to the pharmacy, prescribing practitioner, and the patient. Additionally, a partial fill does not preclude the eventual dispensing of the full amount prescribed. Under the proposed rule, patients requesting a partial fill would be entitled to request that the pharmacist fill the remainder of the prescription within a 30-day window. This alternative would result in no additional consent or notification-related costs and would not impose dispensing delays on patients requesting a partial fill. A further discussion of the benefits and costs of this alternative is described below.

III. Analysis of Benefits and Costs

The proposed rule would allow partial fills of controlled substances in schedule II at the request of the patient or the prescribing practitioner, if not prohibited by State law. The proposed rule also includes time limitations on filling the remaining portions of a partially filled prescription for a schedule II controlled substance, and additional provisions for how a practitioner may request that a prescription for a schedule II controlled substance be partially filled, and how a pharmacy must record the partial filling of a prescription for a schedule II controlled substance.

DEA examined the benefits, costs, and cost savings associated with this proposed rule.

Benefits

DEA does not know all the reasons a prescriber or patient might request a partial fill of a prescription. However, as discussed in the Cost Savings section below, a significant portion of filled opioid prescriptions go unused, leading to the excess opioids being kept by the patient that could be for improper use, diversion, abuse, or improper disposal. Partial filling is expected to reduce the quantity of unused schedule II controlled substances, which would decrease the risk of diversion, and the danger that patients or others may become dependent upon or addicted to prescribed scheduled II controlled substances.

The supply of unused drugs in U.S. households contributes to demand for opioids and illicit drug use. Keeping and storing unused medications in households poses several dangers related to misuse, diversion, accidental overdose, and consumption of spoiled substances.[6] Many patients receive their first opioid prescription after a surgical procedure and frequently retain the majority of unused medication, which could potentially be sold illegally or misused by the patient. In addition, unused medication can be diverted and used by other members of the patient's household, friends of the patient, or sold. According to the National Institute on Drug Abuse, 21 to 29 percent of patients prescribed opioids for chronic pain misuse them, between 8 and 12 percent prescribed opioids for chronic pain develop an opioid use disorder, an estimated 4 to 6 percent who misuse prescription opioids transition to heroin, and about 80 percent of people who use heroin first misused prescription opioids.[7] According to one journal article, ''multiple studies have reported an increased risk of new persistent opioid use after prescription of opioids for acute pain in opioid naïve patients. Even patients who undergo relatively minor low-pain surgery are at increased risk of long term opioid use.'' [8] According to the Substance Abuse and Mental Health Administration (SAMHSA), 51.3 percent of people ''who misused pain relievers in the past year obtained the last pain reliever they misused from a friend or relative.'' [9] Also, although opioid medications are effective in managing acute pain after surgery, even short-term use of opioids can lead to long-term dependence.[10]

The total U.S. economic burden (healthcare costs, criminal justice costs, and lost productivity costs) of prescription opioid misuse in 2013 was estimated to be $78.5 billion, based on the 1.935 million Americans estimated to meet the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM–IV) criteria for opioid use disorder.[11] This economic burden equates to approximately $41,600 per person with opioid use disorder.[12] DEA estimates approximately $41,600 in societal benefit accrues each time we prevent an individual from developing opioid use disorder. This proposed rule is expected to lower the prevalence of opioid misuse and thereby reduce rates of opioid addiction. While DEA has no basis to quantify the amount of misuse that will be prevented, DEA anticipates that reductions in opioid dispensing will reduce the amount of unused opioid medications in American homes, thereby reducing opportunities for medication sharing and other forms of diversion. This, in turn will have a real and significant benefit by reducing misuse and development of opioid use disorder.

Cost Savings

This proposed rule is estimated to lower the amount of schedule II medications dispensed and, therefore, expenditures on prescriptions. It is also expected to reduce the number of unused schedule II controlled substances requiring disposal. To

[6] ''Safe Disposal of Unused Controlled Substances: Current Challenges and Opportunities for Reform,'' Avalere, *http://www.ncdoi.com/osfm/safekids/documents/omd/safedisposalofunusedcontrolledsubstancesreport.pdf.*

[7] ''Opioid Overdose Crisis,'' National Institute on Drug Abuse, *https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.* (Accessed 2/12/2020.)

[8] ''Prescription of opioids for acute pain in opioid naïve patients,'' 2019, Carlos A Pino, MD, Melissa Covington, MD, *Uptodate.com,* Wolters Kluwer. *https://www.uptodate.com/contents/prescription-of-opioids-for-acute-pain-in-opioid-naive-patients.*

[9] ''Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health,'' SAMHSA, *https://www.samhsa.gov/data/report/2018-nsduh-annual-national-report.*

[10] Empowering Post-Surgical Patients to Improve Opioid Disposal: A Before and After Quality Improvement Study Jessica M. Hasak, Carrie L. Roth Bettlach, Katherine B. Santosa, Ellen L. Larson, Jean Stroud, Susan E. Mackinnon Journal of the American College of Surgeons 2017.

[11] Florence CS, Zhou C, Luo F & Xu L, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013,* 54 Med Care 901 (2016). DEA's 2017 National Drug Threat Assessment also references this estimate for total economic burden of prescription drug abuse.

[12] $78.5 billion/1.935 million patients = $40,568 per patient.

quantify the cost savings, DEA estimated the cost of excess medicine and calculated the approximate percent cost savings opportunity that may be realized by this proposed rule.

In 2017, 163,683,029 schedule II prescriptions were filled for ''acute'' pain, with a total retail cost of $11,807,297,373, or an average retail cost of $72.14 per prescription.[13] The prescription data includes a data field that indicates whether the condition being treated is ''acute'' or ''chronic.'' The figure excludes schedule II controlled substances generally prescribed for chronic conditions, *i.e.,* amphetamine, lisdexamfetamine, methamphetamine, and methylphenidate. DEA believes prescriptions for ''acute'' conditions are more likely to be partially filled. Therefore, DEA estimates 163,683,029 prescriptions represent the total number of prescriptions that may be partially filled per year. However, many States have already passed laws or adopted regulations limiting the quantity of schedule II controlled substances that may be dispensed pursuant to a prescription. For example, in 2016, Massachusetts became the first state to pass a law to limit first time opioid prescriptions to seven days.[14] Since 2016, many other States have passed similar laws limiting the prescribing of opioids for acute pain. These limits generally range from a 3 to 14-day supply.[15] As of September 2019, 36 States have placed limits on the amount of opioids that can be prescribed by doctors.[16] The limits in five of those States apply only to Medicaid recipients, and two States have no pill or day limits, but require doctors to prescribe the lowest effective dose.[17] Based on review of state limits for prescribing of opioids, DEA estimates there are 34 states with pill or day limits in place, representing 68.7 percent of the U.S. population.[18] DEA believes partial fill provisions under this proposed rule are likely to have impact on the remaining states without opioid prescription limits, representing 31.3 percent of the U.S. population. Applying this percentage, DEA estimates 51,232,788 (31.3 percent) of the 163,683,029 total prescriptions may be partially filled. According to a 2017 study of post-surgical patients who were prescribed opioids, only 29 percent used the entire prescription, leaving 71 percent of post-surgical patients with excess opioids.[19] The study found that patients prescribed opioids after surgery consumed, on average, only 33 percent of the prescribed medication.[20] Based on that finding, DEA estimates 71 percent of patients will not use all controlled substance prescriptions. DEA therefore estimates that 36,375,279 (71 percent) of the estimated 51,232,788 prescriptions in states without controlled substance prescribing or dispensing limits will not be fully utilized, presenting an opportunity for cost savings from partial fills.

Assuming a typical partial fill request is for 50 percent of the prescription, and as discussed above, a patient is not likely to return to fill the remaining portion of the prescription, the estimated savings from the remaining unfilled portions is 50 percent of the average cost per prescription ($72.14) or $36.07. Multiplying the estimated savings per prescription of $36.07 by the number of prescriptions available for cost savings (36,375,279) results in $1,312,035,331 in potential cost savings per year. However, DEA does not have a basis to estimate the actual number or percentage of controlled substances issued in these states that will be partially filled, and therefore cannot estimate likely aggregate savings based on this methodology. For the purposes of this analysis, DEA estimates 50 percent of potential savings, or $656,028,165 (representing 18,187,640 partially filled prescriptions) will be realized as annual cost savings from reduced schedule II controlled substance dispensing. DEA does not have a basis to estimate the impact of this proposed rule on payments to pharmacies, in terms of price per dosage units, copays, insurance reimbursements, etc., or who would realize the cost savings.

In addition to the cost savings from not dispensing remaining portions of partially filled prescriptions, DEA anticipates cost savings from the reduced need to dispose of unused medications. Patients dispose of unused drugs in a variety of ways, including throwing them in the trash, flushing them down the toilet, pouring them down the sink drain, taking them to the pharmacy or physician's office, or taking them to a drug take back site or event. In a two-phased study using a convenience sample in Southern California, researchers found that only 13 percent of people surveyed either disposed of their medications by taking them to the pharmacy or to the physician's office.[21] For the purpose of this analysis, DEA assumes that only 13 percent of people with leftover schedule II medications dispose of their unused medications in this way. It is likewise estimated that two-thirds of dispensed medications in the United States are unused by patients.[22] Based on DEA's assumption that a typical partial fill represents 50 percent of the prescription, and that the average partially filled prescription represents 67 pills, DEA estimates the average number of excess pills is 34 (50% × 67 pills) per full prescription filled.[23] To calculate the total cost savings for patients not needing to dispose of their unused schedule II drugs, DEA first multiplied the estimated number of partial fill prescriptions by the average disposal pill count to get a total of 618,379,760 pills (18,187,640 × 34). To estimate the number of pills being disposed of by patients through pharmacies, physician offices, or take back days, DEA multiplied the total number of pills (618,679,760) by 13 percent to get 80,389,369 pills. Using the average cost per disposal of $5.60/pound collected,[24] and the estimate of

[13] IQVIA Data 2017. Prescriptions for ''acute pain'' were used to differentiate from ''chronic'' conditions, which are limited to prescriptions for amphetamine. $11,807,297,373/163,683,029 = $72.14.

[14] ''Opioid Prescribing Limits Across the States,'' Marilyn Bullock, PharmD, BCPS, FCCM, 2/5/2019, *pharmacytimes.com.*

[15] Ibid.

[16] ''Opioid prescription limits and policies by state.'' *https://ballotpedia.org/Opioid_prescription_limits_and_policies_by_state.* (Accessed 2/3/2020.)

[17] Ibid.

[18] For the purposes of this discussion, ''State'' includes Puerto Rico and the District of Columbia. Population estimates are based on the U.S. Census Bureau's 2019 population estimates. The 34 States that have pill or day limits are: Alaska, Arizona, Colorado, Connecticut, Delaware, Florida, Hawaii, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia.

[19] Empowering Post-Surgical Patients to Improve Opioid Disposal: A Before and After Quality Improvement Study Jessica M. Hasak, Carrie L. Roth Bettlach, Katherine B. Santosa, Ellen L. Larson, Jean Stroud, Susan E. Mackinnon Journal of the American College of Surgeons 2017. The purpose of the study was to determine whether providing an educational brochure would improve disposal methods of excess opioids. The study found 35 of 128 participants not given the educational brochure used the entire prescription, and 40 of 130 participants given the educational brochure used the entire prescription. Combining the two groups, 75 (29%) of 258 participants used the entire prescription.

[20] Ibid.

[21] ''Taking Stock of Medication Wastage: Unused Medications in US Households.'' NeuroImage, Academic Press, 16 Oct. 2014, *www.sciencedirect.com/science/article/pii/S1551741114003337?via%3Dihub.*

[22] Ibid.

[23] IMS Health IQVIA Data 2017. The 67 average number of pills dispensed was determined by dividing the total number of prescriptions in 2017 by the total number of extended units (10,921,740,149/163,683,029).

[24] Siler, S., Duda, S., Brown, R., Gbemudu, J., Weiner, S., & Glaudemans, J. (n.d.). Safe Disposal

pound/pill of .0069,[25] the total cost savings for unused pills not needing to be disposed of is $3,106,245 (80,389,369 × $5.60 × .0069). The remaining 87 percent of pills that are not properly disposed of are assumed to be either thrown away in the trash (62.7 percent), flushed down the toilet (18 percent), disposed of in the sink (4.3 percent), not disposed of and stored (17.4 percent), and other (8 percent).[26] Therefore, the total annual cost savings of this proposed rule is $659,134,410 ($656,028,165 + $3,106,245).

Costs

DEA estimates there is a cost to prescribers associated with the time burden of writing instructions for partial fill prescriptions.

Partial filling of a prescription for a schedule II controlled substance, pursuant to this proposed rule, may be requested by the prescriber or the patient. The prescriber may request a partial fill by specifying the quantity to be dispensed in the partial filling on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record, along with other information required in 21 CFR 1306.05. While any additional time to specify the quantity to be dispensed in the partial filling may be minimal, especially when viewed in relation to the entire duration of the medical interaction between the prescriber and the patient, DEA estimates each partial fill requested by the prescriber will require 10 additional seconds for the prescriber to specify the quantity to be dispensed. Based on BLS' mean hourly wage for ''29–1060 Physicians and Surgeons'' of $101.43 and a 42.7 percent load for benefits, the estimated loaded hourly wage for a prescriber is $144.74.[27] Therefore, the 10 additional seconds to specify the quantity to be dispensed equates to $0.40.[28] As discussed in the Cost Savings discussion above, DEA does not have a basis to estimate the percentage of the estimated 36,375,279 prescriptions per year available for partial filling that would be partially filled pursuant to this proposed rule. Therefore, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or 18,187,640 prescriptions per year, will be partially filled at the request of the prescriber at an annual cost of $7,275,056.

When a prescribing practitioner has properly specified his or her intent to partially fill a prescription for a schedule II controlled substance, the proposed rule would require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations for other circumstances.[29] Specifically, the dispensing pharmacist would need to make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record (as is currently required under 21 CFR 1306.13(a) when the pharmacist is unable to supply the full quantity called for in the schedule II prescription). Also, for each such partial filling, the pharmacy would be required to maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. DEA believes the most common scenario would be that the partial fill information is entered into a computerized system, in an existing data field; then, an adhesive label with relevant information would be printed, and subsequently affixed to the prescription container. When partially filling a prescription for a schedule II controlled substance at the patient's request, the pharmacist would need to make the same notation on the prescription as when partially filling a prescription at the request of the prescribing practitioner, along with additional information indicating that the patient requested the partial fill. While DEA believes documenting the quantities dispensed for each filled prescription is a usual and ordinary activity for a pharmacist, DEA estimates that it may require 10 additional seconds for a pharmacist to record a partial fill, pursuant to this proposed rule. Based on an estimated loaded median hourly rate of $86.53 for a pharmacist, from the alternatives analysis above, the 10 additional seconds to record partial fills equates to $0.24.[30] As discussed above, DEA does not have a basis to estimate the percentage of the estimated 36,375,279 prescriptions per year that would be partially filled. Therefore, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or 18,187,640 prescriptions per year will be partially filled, requiring recording of the partial fill by the pharmacist at an annual cost of $4,365,034.

If a patient received a partial fill pursuant to this proposed rule, and then returns to the pharmacy to receive another partial fill, or the remainder of the initial prescription, the pharmacist would require some additional time to fill the prescription. For example, if filling the remainder of the partial fill required 10 additional minutes, based on the estimated loaded median hourly rate of $86.53 for a pharmacist, that additional time would equate to a cost of $14.42. Additionally, there would be a similar cost to the patient to potentially make an additional trip to the pharmacy and waiting for the prescription to be filled. However, DEA estimates these additional interactions will be minimal. As discussed earlier in reference to the 2017 study of post-surgical patients who were prescribed opioids, 71 percent of patients in the study did not use the entire prescription, and on average the patients only used 33 percent of the prescribed opioids. If prescribers and patients randomly asked for partial fills, only a small minority of patients would return for the remainder of the prescription. However, DEA does not anticipate the request for partial fills, at the request of the prescriber or the patient, to be random. Rather, DEA anticipates prescribers will exercise professional judgment and foresight in determining when a partial fill is best suited. DEA does not believe a partial fill will be requested by the prescriber when the prescriber believes the patient is likely to need all of the prescribed

of Unused Controlled Substances. Retrieved September 21, 2018, from *http://www.ncdoi.com/osfm/safekids/documents/omd/safedisposalofunusedcontrolledsubstancesreport.pdf.*

[25] *http://michigan-open.org/statewide-drug-takeback-event-nets-900-pounds-of-opioids-more///.*

[26] ''Taking Stock of Medication Wastage: Unused Medications in US Households.'' NeuroImage, Academic Press, 16 Oct. 2014, *www.sciencedirect.com/science/article/pii/S1551741114003337?via%3Dihub.* Percentages are of improper disposal methods only. There were other choices on the survey: Take it to the pharmacy (11.2 percent) and take it to the physician's office (1.8 percent), The percentages do not add to 100 percent because respondents were allow to select more than one method.

[27] BLS, May 2018 National Occupational Employment and Wage Estimates, United States. *https://www.bls.gov/oes/current/oes_nat.htm.* (Accessed 2/6/2020.) BLS, ''Employer Costs for Employee Compensation—September 2019'' (ECEC) reports that average benefits for private industry is 29.9 percent of total compensation. The 29.9 percent of total compensation equates to 42.7 percent (29.9%/70.1%) load on wages and salaries. $101.43 × 1.427 = $144.74. The ''median'' hourly rate is generally preferred. However, the median hourly rate for this occupation code was not available; thus, the ''mean'' was used. While it is likely some of the partial fill instructions will be written by a mid-level practitioner, *i.e.,* nurse practitioner, physician's assistant, etc., or a nurse (in preparation for the prescriber's signature), DEA believes this loaded hourly rate is a reasonably conservative estimate.

[28] 10 seconds × (1 hour / 3,600 seconds) × $144.74/hour = $0.40.

[29] *See* note 2.

[30] 10 seconds × (1 hour / 3,600 seconds) × $86.53/hour = $0.24.

medicine. Furthermore, while the proposed rule would permit patients to request partial fills, DEA believes patients are unlikely to request a partial fill. Rather, the patient would follow the prescriber's instruction, based on consultation between the prescriber and the patient. Therefore, DEA believes any increase in the number of patient-pharmacy interactions related to patient-requested partial fills and resulting burden would likely be *de minimis.* DEA estimates the total cost of this proposed rule is $11,640,090 ($7,275,056 to prescribers and $4,365,034 to pharmacies) per year.

Discussion of Uncertainties

This analysis evaluates the economic impact of activities that were previously not permitted. Therefore, DEA does not have a strong basis to estimate the level of participation in these activities, including partial filling of prescriptions for schedule II controlled substances by prescribers and patients, and how insurance companies would react to these partial filling of prescriptions.

This analysis is highly sensitive to the percentage of prescriptions being partially filled, and the percentage of partially filled prescriptions with patients returning for remainder of the partially filled prescription.

For example, if prescribers and patients in States with no opioid prescription pill or day limits requested a partial fill of 50 percent of the prescription amount for all 71 percent of prescriptions where not all drugs are used, the estimated cost savings from not dispensing the full prescriptions increases to $1,312,035,331 (representing 36,375,279 partially filled prescriptions). Because DEA does not have a good basis to estimate the potential cost savings that will be realized, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or $656,028,165 (representing 18,187,640 partially filled prescriptions) will be realized as cost savings from not dispensing excess schedule II controlled substances. An estimate of zero percent would result in zero cost savings. As the percentage of cases where partial fills are requested increases, the estimated cost savings increase proportionally.

DEA anticipates prescribers will exercise professional judgment and foresight in determining when a partial fill is best suited. DEA does not believe a partial fill will be requested by the prescriber when the prescriber believes the patient is likely to need all of the prescribed medicine, resulting in a minimal number of patients returning for the remainder of the partially filled prescription. Furthermore, while the proposed rule would permit patients to request partial fills, DEA believes of patients are unlikely to request a partial fill. Rather, the patient would follow the prescriber's instruction, based on consultation between the prescriber and the patient.

Finally, this analysis excluded any anticipated impact of this proposed rule on payments to pharmacies, in terms of price per dosage units, copays, insurance reimbursements, etc., or who would realize the cost savings.

DEA welcomes all comments that would narrow the uncertainties in the presented analysis, and specifically asks prescribers, patients, and health care industry, including insurance companies, the following questions:

1. Why do so many prescriptions for schedule II controlled substances result in unused dosages?

2. Would prescribers start using this proposed regulatory provision and start giving instructions for partial filling of schedule II controlled substances, or are there other factors that are likely not to result in prescribers giving partial filling instructions?

3. How often would a prescriber instruct partial filling of a prescription for a schedule II controlled substance?

4. Is it reasonable to anticipate a prescriber will exercise professional judgment and foresight in determining when partial fill would most appropriate, resulting in minimal number of patients returning for the remainder of the partially filled prescription or experiencing pain because they run out of medication? Would prescribers be likely to use consistent criteria for determining when to give partial refills? Given that the majority of schedule II prescriptions are not fully utilized, should prescribers request partial fills in most cases?

5. How likely are patients to request partial filling at the pharmacy when the prescriber has not given instructions for a partial fill on the prescription?

6. Is it reasonable to assume that a patient interested in a partial filling of a schedule II controlled substance would request the prescriber to provide instructions on the prescription?

7. Is it reasonable to assume that when prescribers do not request a partial fill patients will generally not request a partial fill?

8. (Questions for industry including private and public plans and entitlements)

a. What are likely requirements for copay in a partial filling?

b. Would the copay be reduced?

c. Would there be a copay when a patient returns for filling the remainder of a partially filled prescription (full amount or reduced amount)?

d. Would a patient likely spend less on a partial fill than on a full prescription?

e. If so, would requesting two or more partial fills likely cost the patient more than filling the full prescription initially?

Summary

In summary, DEA estimates that the total cost savings of this proposed rule will be $659 million per year, and the total cost will be $12 million per year, for a net cost savings of $647 million per year (rounded to the nearest million dollars). At a three percent discount rate, the net present value of the cost savings over a 5-year period is $2,965 million. At a seven percent discount rate, the present value of the cost savings is $2,655 million. Due to the fluid nature of the national opioid crisis and legislative activity in State government, DEA believes using a five-year term for the present value analysis is reasonable. DEA welcomes public comment on the assumptions made in this analysis.

This proposed rule is expected to be an E.O. 13771 deregulatory action. The proposed rule is an enabling rulemaking, which expands the options for filling schedule II prescriptions. OMB's guidance on E.O. 13771 explains that agencies may carry E.O. 13771 deregulatory actions forward to be applied to E.O. 13771 regulatory actions, and to offset incremental regulatory costs in the same or subsequent fiscal years.[31] Adjusting from 2017 to 2016 dollars, the estimated annual cost savings is $636 million per year over five years, net present value of $2,911 million (cost savings) at three percent discount rate, and $2,606 million (cost savings) at seven percent discount rate to offset future incremental regulatory costs.

Executive Order 12988, Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard of 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

[31] OMB Memorandum M–17–21 at 12.

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, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it, certifies that it will not, if promulgated, have a significant economic impact on a substantial number of small entities.

This proposed rule includes provisions regarding partial fill of prescriptions for schedule II controlled substances. The proposed rule would allow partial fills of prescriptions for controlled substances in schedule II at the request of the patient or the prescribing practitioner, if not prohibited by State law. The proposed rule also includes time limitations on filling the remaining portions of a partially filled prescription for a schedule II controlled substance and additional provisions for how a practitioner may request that a prescription for a schedule II controlled substance be partially filled, how a patient may request that a prescription for a schedule II controlled substance be partially filled, and how a pharmacy must record the partial filling of a prescription for a schedule II controlled substance. While not all practitioners may write prescriptions with partial fill instructions, and not all pharmacies may receive prescriptions for partial fill, these registrants (or entities that employ these registrants) would still be subject to the partial fill provisions contained in the proposed rule.

This proposed rule primarily affects prescribers of schedule II controlled substances and the pharmacies that fill those prescriptions. While prescribers are generally individual practitioners, for the purposes of this analysis, DEA includes industries that employ prescribers. In Table 3, DEA estimates the industries that would be affected by this proposed rule, as described by the North American Industry Classification System (NAICS). This list is not intended to include an exhaustive list of all employers of prescribers of schedule II controlled substances, but rather a representation of primary industries that employ them.

TABLE 3—AFFECTED INDUSTRIES, SIX-DIGIT NAICS CODE

NAICS	NAICS description
446110	Pharmacies and Drug Stores.
621111	Offices of Physicians (except Mental Health Specialists).
621210	Offices of Dentists.
621491	HMO Medical Centers.
621493	Freestanding Ambulatory Surgical and Emergency Centers.
622110	General Medical and Surgical Hospitals.

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) publishes the number of firms, employment, and revenue by firm size and industry. To estimate the number of small businesses affected, DEA compared the 2012 SUSB data, the most recent data available containing revenue by firm size and industry,[32] to the U.S. Small Business Administration (SBA) size standards.[33] DEA estimates a total 326,033 entities, of which 318,362 are small entities, would be affected by this proposed rule. Table 4 details the number of entities, SBA size standard, and estimated number of small entities for each affected industry.[34]

TABLE 4—ESTIMATED NUMBER OF AFFECTED SMALL ENTITIES

NAICS	NAICS description	Firms	SBA size standard, annual revenue ($M)	Small entities
446110	Pharmacies and Drug Stores	18,852	30.0	18,503
621111	Offices of Physicians (except Mental Health Specialists)	174,901	12.0	170,287
621210	Offices of Dentists	125,151	8.0	124,689
621491	HMO Medical Centers	104	35.0	81
621493	Freestanding Ambulatory Surgical and Emergency Centers	4,121	16.5	3,603
622110	General Medical and Surgical Hospitals	2,904	41.5	1,199
Total		326,033	N/A	318,362

Partial filling of a prescription for a schedule II controlled substance, pursuant to this proposed rule, may be requested by the prescriber or the patient. The prescriber may request a partial fill by specifying the quantity to be dispensed in the partial filling on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record, along with other information required in 21 CFR 1306.05. While any additional time to specify the quantity to be dispensed in the partial filling may be minimal, especially when viewed in relation to the entire duration of the medical interaction between the prescriber and the patient, DEA estimates each partial fill requested by the prescriber will require 10 additional seconds for the prescriber to specify the quantity to be dispensed. As discussed in the Costs section above, based on BLS' mean hourly wage for ''29–1060 Physicians and Surgeons'' of $101.43 and a 42.7 percent load for benefits, the estimated loaded hourly wage for a prescriber is $144.74. Therefore, the 10 additional seconds to specify the quantity to be dispensed equates to

[32] ''Number of small businesses: Small entity counts, employment, and revenues . . . number of small entities when the size standard is based on revenue [Link to: *https://www2.census.gov/programs-surveys/susb/tables/2012/us_6digitnaics_r_2012.xlsx*].'' *https://advocacy.sba.gov/resources/the-regulatory-flexibility-act/rfa-data-resources-for-federal-agencies.* (Accessed 2/4/2020.)

[33] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, Effective August 19, 2019. *https://www.sba.gov/document/support--table-size-standards.* (Accessed 2/4/2020.)

[34] For the purposes of this analysis, ''firms'' and ''entities'' are used synonymously.

$0.40.[35] As discussed in the Cost Savings discussion above, DEA does not have a basis to estimate the percentage of the estimated 36,375,279 prescriptions per year available for partial filling that would be partially filled pursuant to this proposed rule. Therefore, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or 18,187,640 prescriptions per year will be partially filled at the request of the prescriber at a cost of $7,275,056. This cost of $7,275,056 equates to an average of $24 per firm, excluding pharmacies.[36]

When a prescribing practitioner has properly specified his or her intent to partially fill a prescription for a schedule II controlled substance, the proposed rule would require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations for other circumstances.[37] Specifically, the dispensing pharmacist would need to make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record (as is currently required under 21 CFR 1306.13(a) when the pharmacist is unable to supply the full quantity called for in the schedule II prescription). Also, for each such partial filling, the pharmacy would be required to maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. DEA believes the most common scenario would be that the partial fill information is entered into a computerized system, in an existing data field; then, an adhesive label with relevant information would be printed, and subsequently affixed to the prescription container. When partially filling a prescription for a schedule II controlled substance at the patient's request, the pharmacist would need to make the same notation on the prescription as when partially filling a prescription at the request of the prescribing practitioner, along with additional information indicating that the patient requested the partial fill. While DEA believes documenting the quantities dispensed for each filled prescription is a usual and ordinary activity for a pharmacist, DEA estimates that it may require 10 additional seconds for the pharmacist to record a partial fill, pursuant to this proposed rule. Based on an estimated loaded median hourly rate of $86.53 for a pharmacist, from the alternatives analysis above, the 10 additional seconds to record partial fills equates to $0.24.[38] As discussed in the Cost Savings section above, DEA does not have a basis to estimate the percentage of the estimated 36,375,279 prescriptions per year that would be partially filled. Therefore, for the purposes of this analysis, DEA estimates the mid-point (50 percent), or 18,187,640 prescriptions per year will be partially filled, requiring recording of the partial fill by the pharmacist at an annual cost of $4,365,034. This cost of $4,365,034 equates to an average of $232 per firm for pharmacies.[39]

The average cost of $24 per firm for prescribers, and $232 per firm for pharmacies is a very high estimate for small entities, as small prescribing firms are expected to request less than an average number of partial fills per firm, and small pharmacies are expected to fill less than average partial fills per firm. Although these are high estimates, these costs were compared to the average annual revenue for the smallest of small entities. The average cost ranges from 0.009 percent of revenue for the smallest of small hospitals, and 0.487 percent for the smallest of small pharmacies. The table below summarizes this analysis for each of the industry codes.

TABLE 5—AVERAGE COST AS PERCENT OF REVENUE

NAICS	NAICS description	Firm size in receipts ($)	Firms	Revenue ($1,000)	Revenue per firm ($)	Cost per firm ($)	Cost as percent of revenue
446110 ...	Pharmacies and Drug Stores	<100,000	757	36,066	47,643	232	0.487
621111 ...	Offices of Physicians (except Mental Health Specialists).	<100,000	15,275	771,280	50,493	24	0.048
621210 ...	Offices of Dentists	<100,000	8,701	452,125	51,962	24	0.046
621491 ...	HMO Medical Centers	<100,000	24	1,266	52,750	24	0.045
621493 ...	Freestanding Ambulatory Surgical and Emergency Centers.	<100,000	223	11,879	53,269	24	0.045
622110 ...	General Medical and Surgical Hospitals	* 100,000–499,999	14	3,812	272,286	24	0.009

* Revenue data not available for "<100,000." Examined smallest size with available revenue data.
Source: SUSB.

After normalizing the cost for revenue size of the affected firms by dividing the total cost by the total revenue for the affected industry, the cost as percent of revenue is much lower. As an industry, the cost as percent of revenue is 0.0005 percent and 0.0018 percent for prescribing firms and pharmacies, respectively. These percentages represent all firms, including small firms. The table below summarizes the normalized cost as percentage of revenue.

TABLE 5—AVERAGE COST AS PERCENT OF REVENUE, NORMALIZED

NAICS	NAICS description	Firm size in receipts	Firms	Revenue ($1,000)	Cost ($)	Cost as percent of revenue
446110 ...	Pharmacies and Drug Stores	All firms	18,852	236,277,373	4,365,034	0.0018
621111 ...	Offices of Physicians (except Mental Health Specialists)	All firms	174,901	402,159,295	7,275,056	0.0005

[35] 10 seconds × (1 hour / 3,600 seconds) × ($101.43/hour × 1.427) = $0.40.

[36] 326,033 total affected firms − 18,852 pharmacies and drug stores = 307,181 firms that employ prescribers. $7,275,056 / 307,181 = $24 (rounded to nearest whole dollar).

[37] *See* note 2.

[38] 10 seconds × (1 hour / 3,600 seconds) × ($60.64/hour × 1.427) = $0.24.

[39] $4,365,034 / 18,852 = $232 (rounded to nearest whole dollar).

TABLE 5—AVERAGE COST AS PERCENT OF REVENUE, NORMALIZED—Continued

NAICS	NAICS description	Firm size in receipts	Firms	Revenue ($1,000)	Cost ($)	Cost as percent of revenue
621210 ...	Offices of Dentists	All firms	125,151	104,740,291		
621491 ...	HMO Medical Centers	All firms	104	7,124,698		
621493 ...	Freestanding Ambulatory Surgical and Emergency Centers.	All firms	4,121	24,084,457		
622110 ...	General Medical and Surgical Hospitals	All firms	2,904	826,654,913		

Source: SUSB.

If a patient received a partial fill pursuant to this proposed rule, and then returns to the pharmacy to receive another partial fill, or the remainder of the initial prescription, the pharmacist would require some additional time to fill the prescription. For example, if filling the remainder of the partial fill required ten additional minutes, based on the estimated loaded median hourly rate of $86.53 for a pharmacist, that additional time would equate to a cost of $14.42. However, DEA estimates these additional interactions will be minimal. As discussed earlier in reference to the 2017 study of post-surgical patients who were prescribed opioids, 71 percent of patients in the study did not use the entire prescription, and on average the patients only used 33 percent of the prescribed opioids. If prescribers and patients randomly asked for partial fills, only a small minority of patients would return for the remainder of the prescription. However, DEA does not anticipate the request for partial fills, at the request of the prescriber or the patient, to be random. Rather, DEA anticipates prescribers will exercise professional judgement and foresight in determining when a partial fill is best suited. DEA does not believe a partial fill will be requested by the prescriber when the prescriber believes the patient is likely to need all of the prescribed medicine. Furthermore, while the proposed rule would permit patients to request partial fills, DEA believes patients are unlikely to request a partial fill. Rather, the patient would follow the prescriber's instructions, based on consultation between the prescriber and the patient. Therefore, DEA believes any increase in the number of patient-pharmacy interactions related to patient-requested partial fills and resulting burden is *de minimis.*

Therefore, DEA's evaluation of economic impact by size category indicates that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of these small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies 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 the UMRA of 1995.

Congressional Review Act

This proposed rule is a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. This proposed rule will result in an annual effect on the economy of $100,000,000 or more; DEA estimates this rule will result in a cost savings of $659 million per year over five years. However, it will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3507(d)), DEA has identified the following collections of information related to this proposed rule. If adopted, this proposed rule would create additional recordkeeping requirements for pharmacies regarding partial fills. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain.*

A. Collections of Information Associated With the Proposed Rule

Title: Recordkeeping Requirements for Partial Fills of Prescriptions for Schedule II Controlled Substances.

OMB Control Number: 1117–NEW.

DEA Form Number: N/A.

DEA is proposing to require pharmacies to create and maintain certain records relating to partial fills of prescriptions for schedule II controlled substances. When presented with a prescription for a schedule II controlled substance, on which the prescribing practitioner has properly specified his/her intent that the prescription be partially filled, the proposed rule would require the pharmacist to record the partial filling in a manner similar to that required under the existing regulations (for other circumstances).[40] Specifically, upon each such partial filling requested by the prescribing practitioner, the dispensing pharmacist would need to make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record (as is currently required under 21 CFR 1306.13(a) when the pharmacist is unable to supply the full quantity called for in the prescription). For electronic prescriptions, there would need to be an electronic prescription record and the record would need to be permanently attached to the electronic prescription. Also, for each such partial filling, the pharmacy would be required to maintain a record with the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions specifically, pharmacy applications would need to allow required information pertaining to

[40] Longstanding DEA regulations, which would not be changed by this proposed rule, also allow the partial filling of a schedule II prescription where the pharmacist is unable to supply the full quantity called for in the prescription (§ 1306.13(a)) and for a patient in a long-term care facility or with a terminal illness (§ 1306.13(b) and (c)).

the quantity, date, and the dispenser to be linked to each electronic controlled substance prescription record (as currently required by 21 CFR 1311.205(b)(10)).

As proposed, upon partially filling a prescription for a schedule II controlled substance at the request of a patient, dispensing pharmacists would need to make a notation on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record of the following: (1) ''patient requested partial fill on [date such request was made]'' and (2) the quantity dispensed. In addition, for each such partial filling, the pharmacy would need to maintain a record of dispensing that includes the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescriptions. For electronic prescriptions specifically, such required information pertaining to the quantity dispensed, date dispensed, and the dispenser would need to be linked to each electronic controlled substance prescription record.

DEA estimates the following number of respondents and burden associated with this collection of information:

- *Number of respondents:* 68,676.
- *Frequency of response:* Per occurrence (264.83255 per year, calculated).
- *Number of responses:* 18,187,640 per year.
- *Burden per response:* 0.002777778 hour (10 seconds).
- *Total annual hour burden:* 50,521 hours.

The activities described in this information collection are usual and ordinary business activities and no additional cost is anticipated.

B. Request for Comments Regarding the Proposed Collections of Information

DEA is soliciting comment on the following issues related to these information collections:

- The need for the information collection and its usefulness in carrying out the proper functions of DEA.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- 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.

Written comments and suggestions from the public and affected agencies concerning the proposed collections of information are encouraged. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117–AB45/Docket No. DEA–469. All comments must be submitted to OMB on or before February 2, 2021. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons set out above, DEA proposes to amend 21 CFR part 1306 as follows:

PART 1306—PRESCRIPTIONS

■ 1. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 823, 829a, 831, 871(b) unless otherwise noted.

■ 2. In § 1306.13, redesignate paragraphs (b) and (c) as paragraphs (c) and (d), and add a new paragraph (b) to read as follows:

§ 1306.13 Partial filling of prescriptions.

* * * * *

(b) Partial filling of a prescription for a schedule II controlled substance at the request of the prescribing practitioner or patient:

(1) *General requirements.* A prescription for a controlled substance in schedule II may be partially filled if all of the following conditions are satisfied:

(i) It is not prohibited by State law;

(ii) The prescription is written and filled in accordance with the Act, this chapter, and State law. A prescription written for a quantity that exceeds the limits of State law is not a valid prescription, therefore, the prescription may not be filled as written. Because such a prescription is not valid, it also cannot be partially filled;

(iii) The partial fill is requested by the patient or by the practitioner who wrote the prescription; and

(iv) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(2) *Time limitations on filling the remaining portions of a partially filled prescription for a schedule II controlled substance.* If all the conditions of paragraph (b)(1) of this section are satisfied, and the prescription is partially filled, remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, must be filled not later than 30 days after the date on which the prescription is written, except that in the case of an emergency oral prescription, as described in subsection 309(a) of the Act (21 U.S.C. 829(a)), the remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, must be filled not later than 72 hours after the prescription is issued.

(3) *How a practitioner may request that a prescription for a schedule II controlled substance be partially filled.* Where a practitioner issues a prescription for a schedule II controlled substance and wants the prescription to be partially filled, the practitioner must specify the quantity to be dispensed in each partial filling on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record. This information must be included on the prescription, along with the other information required by § 1306.05, at the time the practitioner signs the prescription or, in the case of an emergency oral prescription, this information must be communicated by the prescribing practitioner to the pharmacist.

(4) *How a patient may request that a prescription for a schedule II controlled substance be partially filled.* A patient may request that his/her prescription for a schedule II controlled substance be partially filled. Such a request by the patient may be made: In person, in writing if signed by the patient, or by a phone call from the patient to the pharmacist. Where a practitioner has requested the partial filling of a prescription in accordance with paragraph (b)(3) of this section, the patient may not request a partial filling in an amount greater than that specified by the practitioner.

(5) *How a pharmacy must record the partial filling of a prescription for a schedule II controlled substance.* (i) Upon partially filling a prescription at the request of the prescribing practitioner in accordance with paragraph (b)(3) of this section, the pharmacist must make a notation of the quantity dispensed on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record. In addition, for each such partial filling, the pharmacy must maintain a record of dispensing that includes the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions specifically,

such required information pertaining to the quantity dispensed, date dispensed, and the dispenser must be linked to each electronic controlled substance prescription record.

(ii) Upon partially filling a prescription at the request of the patient in accordance with paragraph (b)(4) of this section, the pharmacist must make a notation on the face of the written prescription, in the written record of the emergency oral prescription, or in the electronic prescription record of the following: (I) ''patient requested partial fill on [date such request was made]'' and (II) the quantity dispensed. In addition, for each such partial filling, the pharmacy must maintain a record of dispensing that includes the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescriptions. For electronic prescriptions specifically, such required information pertaining to the quantity dispensed, date dispensed, and the dispenser must be linked to each electronic controlled substance prescription record.

* * * * *

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–26291 Filed 12–3–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 92, 93, 574, 960, 966, 982

[Docket No. FR–6057–P–02]

RIN 2577–AD03

Housing Opportunity Through Modernization Act of 2016: Re-Opening Public Comment Period on Subject of Over Income Families

AGENCY: Office of the General Counsel, HUD.

ACTION: Proposed rule; re-opening of comment period.

SUMMARY: On September 17, 2019, HUD published a proposed rule implementing sections 102, 103 and 104 of the Housing Opportunity through Modernization Act (HOTMA) of 2016. The comment period for the proposed rule closed on November 18, 2019. Among other things, § 960.507 of the rule proposed adding a section addressing the treatment of families in public housing whose family income exceeds the new limit in HOTMA. Before finalizing the rule, HUD seeks additional public comment on the implementation of the public housing income limit, specifically public housing agencies' (PHAs') discretion in addressing over-income families. This notice therefore re-opens the public comment period on the HOTMA proposed rule for an additional 30 days solely to seek comment on these specific issues. HUD is not soliciting comment on any other issues related to HUD's September 17, 2019, proposed rule.

DATES: The comment period for a specific topic in the proposed rule published on September 17, 2019 (84 FR 48820), is re-opened. The due date for comments discussed in this supplemental notice of proposed rulemaking is January 4, 2021.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov*. To receive consideration as public comments, comments must be submitted through one of two methods, specified below. All submissions must refer to the above docket number and title.

1. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov*. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

2. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

FOR FURTHER INFORMATION CONTACT: Aaron Santa Anna, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10282, Washington, DC 20410; telephone number 202–402–5300 (this is not a toll-free number). Individuals with hearing- or speech-impairments may access this number via TTY by calling the toll-free Federal Relay Service during working hours at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On July 29, 2016, the president signed HOTMA into law (Pub. L. 114–201, 130 Stat. 782). HOTMA makes numerous changes to statutes governing HUD programs. In particular, section 103 of HOTMA imposed an income limit on families residing in public housing. Specifically, section 103 provides that two years after the family has reached the income limit, PHAs have the option of requiring families to vacate their units within 6 months or allowing the families to stay, provided the families pay the higher of fair market rent or a rent equal the amount of the monthly subsidy for the unit. HOTMA requires HUD to determine the amount of subsidy through regulation.

On November 29, 2016, HUD published a **Federal Register** notice (81 FR 85996), seeking public input on how HUD should determine the income limit for public housing residents, pursuant to section 103 of HOTMA. HUD followed this notice with a July 26, 2018, notice (83 FR 35490) that made some provisions of section 103 of HOTMA effective.

On September 17, 2019, HUD published a proposed rule to update its regulations according to HOTMA's statutory mandate. Additional details about the proposed rule may be found at 84 FR 48820 (September 17, 2019). In this proposed rule, HUD proposed a new 24 CFR 960.507, which would codify the implementation of treatment of over-income families in public housing, including how to determine the monthly subsidy for such families' units.

While reviewing public comments and developing the final rule, HUD determined that it would be appropriate and helpful to obtain additional public comment on very specific aspects of HUD's implementation of the income limit for public housing. HUD believes that HOTMA provides that families who are over-income (OI) under HOTMA for two consecutive years are no longer public housing tenants eligible for the public housing program and the PHA must terminate the families' participation in the public housing program, even if they are allowed to remain in their units. Because these families would no longer be public housing tenants, they would not be subject to public housing regulations such as 24 CFR part 960 (including income reexamination requirements), and HUD would have no statutory basis to directly regulate these unassisted

families. However, HUD can impose various requirements on the PHAs, which may then be able to require OI families to comply with requirements as a condition of their lease for the unit.

HUD seeks public comment on this determination, the implications of terminating such participation and, as specifically outlined in this notice, what procedural rights, if any, OI families remaining in their unit should be afforded.

II. Questions for Public Comment

HUD is seeking public input on the following questions:

1. Repositioning

For PHAs planning or currently taking advantage of options to convert public housing units under repositioning using one of HUD's repositioning tools such as Rental Assistance Demonstration (RAD), Demolition/Disposition (Section 18) and Streamlined Voluntary Conversion (Section 22), should special considerations regarding relocation apply to OI families permitted to remain in public housing units after the 2-year grace period (the two years after a PHA has first determined a family is over-income before the PHA must terminate the family's tenancy; for more information, see the proposed rule at 84 FR 48828) has ended?

For example, should OI families be afforded any of the tenant protections offered to income-eligible families during conversion? Further, are there any additional implications for the repositioning process that HUD should consider, specifically regarding the possibility of the PHA reducing the number of Tenant Protection Vouchers (TPV) they are eligible for as a result of units being occupied by a non-HUD-assisted family for more than 24 months?

2. Rent and Reexamination & Community Service Activities or Self-Sufficiency Activities (CSSR)

What requirements, if any, in 24 CFR part 960 should apply to OI families that are permitted to remain in public housing units after the 2-year grace period has ended?

Should PHAs have the option to create a preference to allow OI families that have experienced a reduction in income to be immediately re-admitted to the public housing program if they are determined to be income eligible again or should they be considered applicants starting at the bottom of the waiting list?

With respect to CSSR, should HUD give discretion to PHAs to allow for non-public housing leases to contain community service requirements?

3. Dwelling Leases, Procedures and Requirements

What requirements, if any, in 24 CFR part 966 should apply to OI families permitted to remain in public housing units after the 2-year grace period has ended?

Under HOTMA, the only required lease provision for OI families is to charge a rental amount equal to the greater of the fair market rent (FMR) or an alternative rent comprising any amounts from the Operating Fund and Capital Fund under section 9 of the United States Housing Act of 1937 used for the unit. What role should HUD have, if any, specific to non-public housing lease requirements? For example, should HUD mandate minimum lease provisions such as those related to conduct and occupancy restrictions pertaining to drugs, drug-related criminal activity, or lifetime registration as a sex offender?

4. Grievance Procedures and Requirements

Should there be specific grievance or due process rights afforded to OI families permitted to remain in public housing units after the 2-year grace period has ended? At present, if such families are terminated from the public housing program, they would not be afforded the same rights as families that are public housing program participants that are over and above due process rights created by State and local law. What should be HUD's role, if any, in determining or mandating grievance and or due process rights for OI families? With respect to any grievance or due process rights, should discretion be given exclusively to PHAs and deference given to applicable state and local laws?

5. Additional Ramifications

What are the consequences to the families and PHAs if a PHA allows OI families to stay in public housing units while no longer participating in the public housing program? Does such a situation increase or decrease burdens on the families and PHAs? Are there implications for other rights or procedures that have not been discussed above?

III. Justification for Public Comment Period

In accordance with HUD's regulations on rulemaking at 24 CFR part 10, it is HUD's policy that the public comment period for proposed rules should be 60 days. In the past, HUD has generally provided for 60 days for public comment in the case of interim rules as well. However, HUD's policy does not require 60 days for public comment in the case of reopened public comment periods.

HUD solicited input on the implementation of over-income provisions multiple times, and this is a very narrow solicitation of additional comments. If HUD determines to adopt any suggestions that may be made in the public comments in the final rule, HUD would like to be able to do so as quickly as possible so that the final rule can be published in an expedient manner.

For these reasons, HUD has determined that in this case a 30-day public comment period is appropriate.

IV. Solicitation of Comment Only on Over-Income Provisions

This solicitation of public comment is solely on the specific questions pertaining to the over-income provisions as provided in this supplemental notice of proposed rulemaking. This notice is not re-opening public comment on any other issues related to HUD's September 17, 2019 proposed rule, and HUD will not review or consider public comments that address issues other than the specific questions in this document directed to the over-income provisions.

Aaron Santa Anna,

Associate General Counsel for Legislation and Regulations.

[FR Doc. 2020–26197 Filed 12–3–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 90

[212A2100DD/AAKC001030/A0A501010.999900]

RIN 1076–AF58

Election of Officers of the Osage Minerals Council

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Indian Affairs (BIA) proposes to revise its regulations governing elections of the Osage Nation to update and limit the Secretary's role to the task of compiling a list of voters for Osage Minerals Council elections. These proposed changes would reaffirm the inherent sovereign rights of the Osage Tribe to determine its membership and form of government.

DATES: Please submit your comments by February 2, 2021.

ADDRESSES: You may submit comments, identified by the number 1076–AF58, by any of the following methods:

- *Federal rulemaking portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: consultation@bia.gov.* Include the number 1076–AF58 in the subject line of the message.
- *Mail or courier:* Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action, Office of the Assistant Secretary—Indian Affairs, U.S. Department of the Interior, 1849 C Street NW, Mail Stop 4660, Washington, DC 20240.

We cannot ensure that comments received after the close of the comment period (see **DATES**) will be included in the docket for this rulemaking and considered. Comments sent to an address other than those listed above will not be included in the docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action, telephone (202) 273–4680, *elizabeth.appel@bia.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory Authority

BIA is proposing this rule under the authority of the Act of June 28, 1906, Public Law 59–321, 34 Stat. 539, as amended by the Act of December 3, 2004, Public Law 108–431, 118 Stat. 2609.

II. Background

A. History of the Rule

The Department of the Interior provided testimony in support of the legislation proposed by the Osage Nation when the Nation sought to exercise its inherent sovereign rights. Thereafter, the United States Congress reaffirmed in 2004 the Nation's rights to determine its membership and form of government. The following discussion sets forth a brief historical account of the relationship between the Osage Nation and the Federal government.

In 1906, Congress enacted the Osage Allotment Act, which is unique among Federal Indian laws in that it restricts the Osage Nation from defining its own membership rules, and prescribes a particular form of government, which the Nation could not change without seeking amendment or clarification of Federal law. In 2002, the 31st Osage Tribal Council, formed pursuant to the Osage Allotment Act, actively began seeking a legislative remedy to address the restrictions contained in the Osage Allotment Act.

On July 25, 2003, Congressman Frank Lucas (R–OK) introduced H.R. 2912, a bill reaffirming the rights of the Osage Nation to form its own membership rules and tribal government, provided that no rights to any shares in the mineral estate of the Nation's reservation are diminished. The bill also directs the Secretary of the Interior to assist the Nation in holding appropriate elections and referenda at the request of the Nation.

H.R. 2912 was referred to the Committee on Resources. On March 15, 2004, that Committee held a hearing on the bill in Tulsa, Oklahoma. Osage Nation officials, BIA representatives, and Osage people testified in favor of the bill. On May 5, 2004, the bill was favorably reported to the House of Representatives by unanimous consent. See H. Rpt. 108–502. On June 1, 2004, the House of Representatives passed the bill and then sent it to the Senate, and it was referred to the Committee on Indian Affairs.

On July 14, 2004, the Committee on Indian Affairs favorably reported H.R. 2912 to the Senate with a ''do pass'' recommendation. President Bush signed H.R. 2912 into law on December 3, 2004, and became Public Law 108–431, 118 Stat. 2609.

The Commission began conducting town hall meetings in April 2005. Meetings were conducted in all Osage communities and other geographic areas with large concentrations of Osages. This was followed by a written survey mailed to all Osages with a Certificate of Degree of Indian Blood (CDIB) card. Input from the meetings and data obtained from the survey results were compiled to formulate key questions put forward to the Osage people for a vote in a referendum in November 2005.

The results from the referendum were used to draft an Osage Constitution, which was ratified on March 11, 2006, in a second referendum vote. The Osage Nation adopted a new constitutional form of government reorganized from a Tribal Council system into a tripartite system, which now includes an executive, legislative and judicial branch with a separation of powers between the three branches.

This was followed on June 5, 2006, by the election of a Principal Chief and Assistant Principal Chief, Osage Nation Congress, and Osage Minerals Council. At the request of the Nation, the BIA provided technical assistance in conducting the election in accordance with Public Law 108–431, 118 Stat. 2609. With the elections completed, all elected officials were sworn into their respective offices on July 3, 2006. Upon the swearing in of these elected officials, governmental authority passed from the Osage Tribal Council to the Osage Nation Constitutional Government. Thereafter, the Osage Tribe of Indians of Oklahoma became the Osage Nation.

In 2008, the BIA formally acknowledged the name change of the Tribe from the Osage Tribe of Indians of Oklahoma to the Osage Nation and published the change in the **Federal Register** in the list of Indian Entities Recognized and Eligible to Receive Services from the United States Bureau of Indian Affairs. (See, 73 FR 18553, April 4, 2008.) Further communication between the Nation and the BIA eventually resulted in an agreement to begin an informal negotiated rulemaking process. In February 2010, representatives from the Osage Nation, the BIA Osage Agency, the BIA Eastern Oklahoma Regional Office, the Tulsa Field Solicitor's Office, and the BIA Central Office convened to form a joint regulation negotiation team. The team completed new and revised regulations to cover 25 CFR parts 90, 91, 117, and 158. The June 2010 Election resulted in a change of administration of the Osage Nation, thereby, starting the process over again with a new vision from Osage Nation. The Osage Nation formed a new team in 2019 and they have reviewed and revised regulations to cover 25 CFR part 90. The team will continue working on parts 91, 117, and 158.

B. The Need for This Proposed Rulemaking

Both the BIA and the Osage Nation recognized the need to update Federal regulations related specifically to the Osage Nation so that the regulations align with the Osage Nation's new form of government and address outdated regulations. In doing so, the parties

agreed to participate in informal rulemaking. This consensus-oriented process conducted between the BIA and the Osage Nation afforded an opportunity to collaborate and identify a rulemaking strategy to address issues and concerns contained in the regulations specifically affecting the Osage. The proposed rulemaking will clarify the BIA's role to better meet its fiduciary trust responsibilities and carry out the policies established by Congress to strengthen tribal sovereignty on a government-to-government basis. This rulemaking will also provide the BIA with the tools to more effectively and consistently manage trust assets and better serve the Osage Nation and Osage people.

III. Overview of Proposed Rule

This rule governs BIA's role in providing information to the Osage Minerals Council Election Board for purposes of notice. The existing 25 CFR part 90 is the authority for the release of otherwise potentially confidential information to the Osage Minerals Council Election Board. The alternative to these amendments would deprive the Osage Nation of the information it needs to accurately identify Osage voters. Amendments to this part focus on the BIA's procedures in compiling a complete annuitant list with addresses and headright interests to the Osage Minerals Council Election Board for purposes of identifying Osage voters.

This proposed rule would delete most provisions of part 90 in their entirety because of the enactment of the Public Law 108–431, 118 Stat. 2609, and subsequent adoption of the Constitution of the Osage Nation. Thus, the remaining purpose of this part is the authority for BIA to provide a list to the Osage Minerals Council Election Board of eligible headright interest owners in the manner requested by the Osage Nation. The Department may not generally release this information but this part provides authority for the release solely to the Osage Minerals Council Election Board for purposes of conducting elections for the Osage Minerals Council. The Privacy Act does not prohibit disclosure of the headright interests of eligible Osage voters for this purpose. The Department may provide the list of eligible headright interest owners as a routine use under the Privacy Act.

In response to the Constitution of the Osage Nation, the BIA significantly reduced its role in the elections of the Osage Nation as of June 2006. The only remaining portion in part 90 describes the current role of the BIA in the Osage Minerals Council election process.

The following distribution table indicates where each of the current regulatory sections in 25 CFR part 90 is located in the proposed 25 CFR part 90.

Current 25 CFR §	Proposed 25 CFR §	Title	Description of change
N/A	90.100	What role does BIA play in the Osage Minerals Council elections?.	Consolidated current §§ 90.21 and 90.35 into one new section.
90.1	N/A	General, Definitions	Deleted.
90.2	N/A	General, Statutory provisions	Deleted.
90.21	N/A	Eligibility, General	Revised and incorporated into the new § 90.100.
90.30	N/A	Elections, Nominating conventions and petitions	Deleted.
90.31	N/A	Elections, Applicability	Deleted.
90.32	N/A	Elections, Election Board	Deleted.
90.33	N/A	Elections, Watchers and challengers	Deleted.
90.34	N/A	None (Apparently omitted)	
90.35	N/A	Elections, List of voters	Revised and redesignated as § 90.100 (see first row).
90.36	N/A	Elections, Disputes on eligibility of voters	Deleted.
90.37	N/A	Elections, Election Notices	Deleted.
90.38	N/A	Elections, Opening and closing of poll	Deleted.
90.39	N/A	Elections, Voters to announce name and residence	Deleted.
90.40	N/A	Elections, Ballots	Deleted.
90.41	N/A	Elections, Absentee voting	Deleted.
90.42	N/A	Elections, Absentee ballots	Deleted.
90.43	N/A	Elections, Canvass of election returns	Deleted.
90.44	N/A	Elections, Statement of supervisor	Deleted.
90.46	N/A	Elections, Notification of election of tribal officers	Deleted.
90.47	N/A	Elections, Contesting elections	Deleted.
90.48	N/A	Elections, Notice of Contest	Deleted.
90.49	N/A	Elections, Expenses of elections	Deleted.

IV. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866, 13563, and 13771)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. 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. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements. This proposed rule is also part of the Department's commitment under the Executive Order to reduce the number and burden of regulations.

E.O. 13771 of January 30, 2017, directs Federal agencies to reduce the regulatory burden on regulated entities

and control regulatory costs. OIRA has determined that this rule is deregulatory because the updates will dramatically reduce the role of the Federal government in Osage Nation elections of officers.

B. The Regulatory Flexibility Act

The Department of the Interior certifies that this proposed rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

C. Small Business Regulatory Enforcement Fairness Act of 1996

This proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. Because this proposed rule is exclusively confined to the Federal Government, Osage Indians, and the Osage Nation, this rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandates Reform Act of 1995

This proposed rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The proposed rule does not have a monetarily 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.

E. Takings (E.O. 12630)

This proposed rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630 because this proposed rule does not affect individual property rights protected by the Fifth Amendment or involve a compensable ''taking.'' A takings implication assessment is not required.

F. Federalism (E.O. 13132)

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. A federalism summary impact statement is not required.

G. Civil Justice Reform (E.O. 12988)

This proposed rule complies with the requirements of Executive Order 12988. Specifically, this rule: (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it has substantial direct effects on one federally recognized Indian Tribe because the rule directly addresses the Osage Nation. The Department consulted with the Osage Nation on this proposed rule prior to its publication. This rulemaking is a result of a consensus-oriented process conducted between the Department of the Interior and the Osage Nation to identify a rulemaking strategy to address issues and concerns contained in the regulations related specifically to the Osage Nation, which no longer align with the Nation's form of government. The purpose of today's proposed rulemaking is to allow the Department of the Interior to better meet its fiduciary trust responsibilities and to carry out the policies established by Congress to strengthen Tribal sovereignty with regard to elections of Osage Nation officers.

I. Paperwork Reduction Act

This proposed rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. 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.

J. National Environmental Policy Act

This proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because this is an administrative and procedural regulation. (For further information see 43 CFR 46.210(i).) We have also determined that this proposed rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Effects on the Energy Supply (E.O. 13211)

This proposed rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

L. Clarity of This Regulation

We are required by Executive Orders 12866 (section 1(b)(12)), and 12988 (section 3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each proposed rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and,

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you believe lists or tables would be useful, etc.

M. Public Availability of Comments

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.

List of Subjects in 25 CFR Part 90

Elections, Indians—tribal government.

For the reasons given in the preamble, the Department of the Interior proposes

to amend Chapter 1 of Title 25 of the Code of Federal Regulations by revising part 90 to read as follows.

PART 90—ELECTIONS OF OSAGE MINERALS COUNCIL

Authority: 5 U.S.C. 301; 25 U.S.C. 2, 9; Sec. 9, 34 Stat. 539; 118 Stat. 2609.

§ 90.100 What role does BIA play in the Osage Minerals Council's elections?

(a) The Superintendent of the Osage Agency must compile, at the request of the Chair of the Osage Minerals Council, a list of the voters of Osage descent who will be 18 years of age or over on the election day designated by the Osage Minerals Council and whose names appear on the quarterly annuity roll at the Osage Agency as of the last quarterly payment immediately preceding the date of the election. Such list must set forth only the name and last known address of each voter.

(b) For purposes of calculating votes, the Superintendent must furnish to the supervisor of the Osage Minerals Council Election Board a separate list containing the name and last known address of each eligible voter and including the voter's headright interest shown on the last quarterly annuity roll.

Tara Sweeney.

Assistant Secretary—Indian Affairs.

[FR Doc. 2020–25999 Filed 12–3–20; 8:45 am]

BILLING CODE 4337–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[EPA–HQ–OPP–2020–0124; FRL–10012–21]

RIN 2070–AJ49

Notification of Submission to the Secretary of Agriculture; Pesticides; Proposal of Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of submission to the Secretary of Agriculture.

SUMMARY: This document notifies the public as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that the EPA Administrator has forwarded to the Secretary of the United States Department of Agriculture (USDA) a draft regulatory document concerning ''Pesticide Product Performance Data Requirements for Products Claiming Efficacy Against Certain Invertebrate Pests.'' The draft regulatory document is not available to the public until after it has been signed and made available by EPA.

DATES: See Unit I. under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2020–0124, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

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

FOR FURTHER INFORMATION CONTACT: Sara Kemme, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–8533; email address: *Kemme.Sara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What action is EPA taking?

Section 25(a)(2)(A) of FIFRA requires the EPA Administrator to provide the Secretary of USDA with a copy of any draft proposed rule at least 60 days before signing it in proposed form for publication in the **Federal Register**. The draft proposed rule is not available to the public until after it has been signed by EPA. If the Secretary of USDA comments in writing regarding the draft proposed rule within 30 days after receiving it, the EPA Administrator shall include those comments and EPA's response to those comments with the proposed rule that publishes in the **Federal Register**. If the Secretary of USDA does not comment in writing within 30 days after receiving the draft proposed rule, the EPA Administrator may sign the proposed rule for publication in the **Federal Register** any time after the 30-day period.

II. Do any statutory and Executive Order reviews apply to this notification?

No. This document is merely a notification of submission to the Secretary of USDA. As such, none of the regulatory assessment requirements apply to this document.

List of Subjects in Part 40 CFR Part 158

Environmental protection, administrative practice and procedure, agricultural and non- agricultural, pesticides and pests, reporting and recordkeeping requirements.

Dated: November 24, 2020.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2020–26702 Filed 12–3–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 227 and 252

[Docket DARS–2020–0033]

RIN 0750–AK84

Defense Federal Acquisition Regulation Supplement: Small Business Innovation Research Program Data Rights (DFARS Case 2019–D043)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Announcement of meeting; reopening of comment period.

SUMMARY: DoD is hosting a public meeting to engage in discussion and obtain views of experts and interested parties in Government and the private sector regarding implementation in the Defense Federal Acquisition Regulation Supplement (DFARS) of the data rights portions of the Small Business Innovation Research Program and Small Business Technology Transfer Program Policy Directives.

DATES: *Submission of Comments:* The comment period for the advance notice of proposed rulemaking published on August 31, 2020 (85 FR 53758), is reopened. Submit any comments on the advance notice of proposed rulemaking in writing to the address shown in **ADDRESSES** on or before January 31, 2021, to be considered in formation of the proposed rule.

Public Meeting: A virtual public meeting will be held on January 14, 2021, from 12:30 p.m. to 4:30 p.m. Eastern time. The public meeting will end at the stated time, or when the discussion ends, whichever comes first. DoD will also reserve January 15, 2021, from 12:30 p.m. to 4:30 p.m. Eastern time, if DoD determines additional discussion is necessary.

Registration: Registration to participate in this meeting must be received no later than close of business on January 7, 2021. Information on how to register for the public meeting may be found in the **SUPPLEMENTARY INFORMATION** section of this notice.

ADDRESSES:

Public Meeting: A virtual public meeting will be held using Microsoft video conferencing software.

Submission of Comments: Submit comments identified by DFARS Case 2019–D043, using any of the following methods:

o *Federal eRulemaking Portal: http://www.regulations.gov.* Search for ''DFARS Case 2019–D043.'' Select ''Comment Now'' and follow the instructions provided to submit a comment. Please include ''DFARS Case 2019–D043'' on any attached documents.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2019–D043 in the subject line of the message.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Kimberly Ziegler, OUSD(A&S)DPC/DARS, Room 3B938, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Ziegler, telephone 571–372–6095.

SUPPLEMENTARY INFORMATION: DoD is interested in continuing a dialogue with experts and interested parties in Government and the private sector regarding amending the DFARS to implement the intellectual property (*e.g.,* data rights) portions of the revised Small Business Innovation Research (SBIR) Program and Small Business Technology Transfer (STTR) Program Policy Directives. Previously, DoD published an advance notice of proposed rulemaking (ANPR) on August 31, 2020, at 85 FR 53758, providing draft DFARS revisions and requesting written public comments.

Registration: Individuals wishing to participate in the virtual meeting must register by January 7, 2021, to facilitate entry to the meeting. Interested parties may register for the meeting by sending the following information via email to *osd.dfars@mail.mil* and include ''Public Meeting, DFARS Case 2019–D043'' in the subject line of the message:

- Full name.
- Valid email address, which will be used for admittance to the meeting.
- Valid telephone number, which will serve as a secondary connection method. Registrants must provide the telephone number they plan on using to connect to the virtual meeting.
- Company or organization name.
- Whether the individual desires to make a presentation.

Pre-registered individuals will receive instructions for connecting using the Microsoft video conferencing software not more than one week before the meeting is scheduled to commence.

Presentations: Presentations will be limited to 5 minutes per company or organization. This limit may be subject to adjustment, depending on the number of entities requesting to present, in order to ensure adequate time for discussion. If you wish to make a presentation, please submit an electronic copy of your presentation via email to *osd.dfars@mail.mil* no later than the registration date for the specific meeting. Each presentation should be in PowerPoint to facilitate projection during the public meeting and should include the presenter's name, title, organization affiliation, telephone number, and email address on the cover page.

Correspondence, Comments, and Presentations: Please cite ''Public Meeting, DFARS Case 2019–D043'' in all correspondence related to the public meeting. There will be no transcription at the meeting. The submitted presentations will be the only record of the public meeting and will be posted to the following website at the conclusion of the public meeting: *https://www.acq.osd.mil/dpap/dars/technical_data_rights.html.*

The comment period for the proposed rule is reopened and extended through January 31, 2021, to provide additional time for interested parties to comment on the proposed DFARS changes.

List of Subjects in 48 CFR Parts 227 and 252

Government procurement.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2020–26741 Filed 12–3–20; 8:45 am]

BILLING CODE 5001–06–P

Notices

Federal Register

Vol. 85, No. 234

Friday, December 4, 2020

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

December 1, 2020.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: 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; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and 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.

Comments regarding these information collections are best assured of having their full effect if received by January 4, 2021. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *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.

An agency 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.

National Agricultural Statistics Service

Title: Fast Track Generic Clearance for the Collection of Qualitative Feedback on Customer Satisfaction Surveys.

Omb Control Number: 0535–0261.

Summary of Collection: Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to ensure that our programs are effective and meet our users' needs, the National Agricultural Statistics Service (NASS) seeks to obtain OMB approval for the renewal of this generic clearance to collect qualitative feedback on our products and services. The qualitative information to be collected is intended to provide useful insights on user perceptions and opinions. It is not intended to yield quantitative results that are statistically generalizable to any larger populations.

Need and Use of the Information: This collection of information is necessary to enable NASS to obtain feedback in an efficient, timely manner, in accordance with our commitment to improving the quality, usability, and ease of accessing our surveys and public information. This feedback will provide insights into user perceptions, experiences, expectations, and provide an early warning of issues with service; and focus attention on areas where communication, training, or changes in operations might improve delivery of products and services. These collections will allow for ongoing, collaborative, and actionable communications between NASS and its customers and stakeholders. The feedback will also contribute directly to the improvement of program management.

NASS will collect, analyze, summarize, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current products and services and make improvements based on the collected feedback. 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 used to plan and inform efforts to improve 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.

Description of Respondents: Farms; Business or other for-profit; Not-for-profit Institutions and State, Local or Tribal Government.

Number of Respondents: 120,000.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 8,375.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–26755 Filed 12–3–20; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

December 1, 2020.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: 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; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and 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.

Comments regarding these information collections are best assured of having their full effect if received by January 4, 2021. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *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.

An agency 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.

National Agricultural Statistics Service

Title: Fruits, Nut, and Specialty Crops.

OMB Control Number: 0535–0039.

Summary of Collection: The primary function of the National Agricultural Statistics Service (NASS) is to prepare and issue current official state and national estimates of crop and livestock production. Estimates of fruit, tree nuts, and specialty crops are an integral part of this program. These estimates support the NASS strategic plan to cover all agricultural cash receipts. The authority to collect these data activities is granted under U.S. Code title 7, Section 2204(a). Information is collected on a voluntary basis from growers, processors, and handlers through surveys.

Need and Use of the Information: Data reported on fruit, nut, and specialty crops are used by NASS to estimate crop acreage, yield, production, utilization, price, and value in States with significant commercial production. These estimates are essential to farmers, processors, importers and exporters, shipping companies, cold storage facilities and handlers in making production and marketing decisions. Estimates from these inquiries are used by market order administrators in their determination of expected crop supplies under federal and State market orders.

Description of Respondents: Farms; Business or other for-profit.

Number of Respondents: 74,410.

Frequency of Responses: Reporting: On occasion; Annually; Semi-annually; Quarterly; Monthly; Weekly.

Total Burden Hours: 31,603.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–26731 Filed 12–3–20; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

December 1, 2020.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding 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; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and 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.

Comments regarding this information collection received by January 4, 2021 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *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.

An agency 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.

Food Safety and Inspection Service

Title: Salmonella Initiative Program.

OMB Control Number: 0583–0154.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*). These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged. The *Salmonella* Initiative Program (SIP) offers incentives to meat and poultry slaughter establishments to control *Salmonella* in their operations. SIP benefits public health because it encourages establishments to test for microbial pathogens, which is a key feature of effective process control.

Need and Use of the Information: Under SIP, establishments will share their data with the Food Safety and Inspection Service (FSIS); this will help the Agency in formulating its policy. Establishments that want to enter SIP must send a protocol to FSIS informing the Agency about their plans for implementing SIP in their establishment, including data collection, objectives and methods of evaluating the new technology for which they are receiving the regulator waiver.

Description of Respondents: Business or other for-profit.

Number of Respondents: 79.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 17,628.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–26717 Filed 12–3–20; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Coconino and Tonto National Forests; Arizona; Fossil Creek Wild and Scenic River Comprehensive River Management Plan

AGENCY: Forest Service, USDA.

ACTION: Notice of opportunity to object to the Fossil Creek Wild and Scenic River Comprehensive River Management Plan, Forest Plan Amendments, Final Environmental Impact Statement and Draft Record of Decision.

SUMMARY: The Coconino and Tonto National Forests, located in Arizona, have prepared a Comprehensive River Management Plan (CRMP) for the Fossil Creek Wild and Scenic River. Significant programmatic forest plan amendments to the Coconino and Tonto National Forests land management plans, to incorporate management direction from the CRMP have also been prepared for the Fossil Creek Wild and Scenic River. Because the project includes two separate decisions, this notice initiates two separate but concurrent pre-decisional objection

filing periods. Objections to the proposed CRMP must be filed within 45 days of the publication date of this notice and objections to the proposed amendments to the land management plans must be filed withn 60 days of the publication date of this notice. The accompanying Final Environmental Impact Statement and draft Record of Decision describe the actions and analyze the effects of site specific activities associated with the CRMP and the forest plan amendments.

DATES: The Forest Plan Amendments, CRMP, FEIS, Draft ROD, and other project related documents will be available on the project web page: *https://www.fs.usda.gov/project/?project=27457* starting December 4, 2020.

A legal notice of the initiation of the 60-day and 45-day objection periods is also being published in the *Arizona Daily Sun* and the *Arizona Capitol Times* and will provide additional clarity and specific objection requirements found in the 36 CFR 218 and 36 CFR 219 regulations (*https://www.ecfr.gov/cgi-bin/text-idx?SID=a45353900f749741bde9364d9d74dd04&mc=true&node=pt36.2.218&rgn=div5 and https://www.ecfr.gov/cgi-bin/text-idx?SID=a45353900f749741bde9364d9d74dd04&mc=true&node=pt36.2.219&rgn=div5*). The date the legal notice is published in the *Arizona Daily Sun* is the exclusive means for calculating the time to file an objection. Please reference regulatory requirements for filing an objection in the above links. A copy of these legal notices will be posted on the website described above.

ADDRESSES: Objections may be submitted to Sandra Watts, Acting Regional Forester, filed via mail or express delivery to 333 Broadway Blvd. SE, Albuquerque, NM 87102; by facsimile to FAX: (505) 842–3800; by email to *objections-southwestern-regional-office@usda.gov.* An automated response will confirm the electronic objection has been received. The email subject or fax coversheet must include a subject line with ''Fossil Creek Comprehensive River Management Plan Objection'' or ''Fossil Creek CRMP FEIS'' and should specify the number of pages being submitted. If an automated response is not received, it is the sender's responsibility to ensure timely filing by other means. Electronic objections must be submitted in MS Word, Word Perfect, portable document format (PDF), or rich text format (RTF).

FOR FURTHER INFORMATION CONTACT: Project Leader, Mike Dechter, *mike.dechter@usda.gov,* by phone at 928–527–3416. For media inquiries or to leave a message about the project, please contact Brady Smith via email at *brady.smith@usda.gov* or leave a voicemail at 928–527–3490.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: This proposed CRMP is subject to the objection process pursuant to 36 CFR 218 Subparts A and B, and the Forest Plan amendments are subject to the objection process pursuant to 36 CFR 219 Subparts A and B. Objections to the Fossil Creek Comprehensive River Management Plan or to the Forest Plan amendments will only be accepted from those who have previously submitted timely comments regarding these planning efforts during any designated opportunity for public comment, unless based on information not available during an earlier designated opportunity for public comment (*i.e.,* new information).

Both objection processes under 36 CFR 218 and 36 CFR 219 Subpart B provide an opportunity for members of the public who have participated in the planning process for the Fossil Creek Wild and Scenic River Comprehensive River Management Plan to have any unresolved concerns reviewed by the Forest Service prior to a final decision by the Responsible Officials.

It is the responsibility of the objector to ensure that the reviewing officer receives the objection in a timely manner. The regulations prohibit extending the length of the objection filing period. Please reference regulatory requirements for objecting at the link provided above, under dates.

Responsible Officials

The responsible officials who will approve the record of decision for the Fossil Creek Wild and Scenic River CRMP are Laura Jo West, Forest Supervisor for the Coconino National Forest and Neil Bosworth, Forest Supervisor of the Tonto National Forest.

The Regional Forester is the reviewing officer for all decisions related to the CRMP and its associated activities and the plan amendment since the Forest Supervisors are the deciding officials (36 CFR 219.56(e)(2)).

Jennifer Eberlien,

Associate Deputy Chief, National Forest System.

[FR Doc. 2020–26687 Filed 12–3–20; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Montana 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 teleconference meeting of the Montana Advisory Committee (Committee) to the Commission will be held at 12:00 p.m. (Mountain Time) on Tuesday, December 15, 2020. The purpose of the meeting will be to brainstorm potential topics for civil rights project.

DATES: The meeting will be held on Tuesday, December 15, 2020 at 12 p.m. MT.

Public Call Information:
Dial: 800–367–2403.
Conference ID: 3007689.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or by phone at (202) 681–0857.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 800–367–2403, conference ID number: 3007689. 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.*

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=a10t0000001gzlyAAA.* 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, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Orientation Presentation (Refresher)
III. Discuss Civil Rights Topics
  a. COVID–19 and the Native American Community
  b. COVID–19 and Health Disparities Across Races
  c. Subminimum Wages for People With Disabilities
  d. FEMA's Natural Disaster Response
  e. Hate Groups in Montana and Their Impacts
  f. Montana Policing Practices
IV. Nominate Vice Chair
V. Public Comment
VI. Discuss Next Steps
VII. Adjournment

Dated: November 30, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–26656 Filed 12–3–20; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Hawai'i 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 teleconference meeting of the Hawai'i Advisory Committee (Committee) to the Commission will be held from 10 a.m. to 11:30 a.m. on Wednesday, December 16, 2020 (Hawaiian Time). The purpose of the meeting will be to debrief their web hearings on COVID–19 and its impact on Pacific Islander communities.

DATES: The meeting will be held on Wednesday, December 16, 2020 from 10:00 a.m.–11:30 a.m. HST.

Public Call Information:
Dial: 800–367–2403.
Conference ID: 1129338.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, Designated Federal Officer (DFO) at *afortes@usccr.gov* or by phone at (202) 681–0857.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 800–367–2403, conference ID number: 1129338. 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.*

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=a10t0000001gzl0AAA.* 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. Discussion Regarding Testimonies
III. Public Comment
IV. Next Steps

Dated: November 30, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–26655 Filed 12–3–20; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[11/13/2020 through 11/25/2020]

Firm name	Firm address	Date accepted for investigation	Product(s)
Reliable Castings Corporation	3530 Spring Grove Avenue, Cincinnati, OH 45223.	11/13/2020	The firm manufactures miscellaneous metal parts for motor vehicles.
Custom Wood Products, Inc	300 Corporate Drive, Charles City, IA 50616.	11/13/2020	The firm manufactures furniture for recreational motor vehicles.
Dionysus Acquisition, LLC, d/b/a Carolyn's Sakonnet Vineyard.	162 West Main Road, Little Compton, RI 02837.	11/19/2020	The firm produces wine.
AIR802 Corporation	1981 Wiesbrook Drive, Oswego, IL 60543.	11/20/2020	The firm manufactures telecommunications equipment.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE—Continued

[11/13/2020 through 11/25/2020]

Firm name	Firm address	Date accepted for investigation	Product(s)
Moore-Merkowitz Tile, Ltd	5595 Cook Road, Alfred Station, NY 14803.	11/24/2020	The firm manufactures ceramic tiles.
Associated Machine Design, Inc	610 Baeten Road, Green Bay, WI 54304.	11/24/2020	The firm manufactures machinery for making paper and paperboard.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Bryan Borlik,

Director.

[FR Doc. 2020–26683 Filed 12–3–20; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–209–2020]

Foreign-Trade Zone 37—Orange County, New York; Application for Subzone; JJS Transportation and Distribution Co Inc Valley Stream, New York

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the County of Orange, grantee of FTZ 37, requesting subzone status for the facility of JJS Transportation and Distribution Co Inc, located in Valley Stream, New York. 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 November 25, 2020.

The proposed subzone (0.69 acres) is located at 145 Hook Creek Boulevard, Valley Stream, Nassau County, New York. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 37.

In accordance with the FTZ Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

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 January 13, 2021. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 28, 2021.

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 Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov.*

Dated: November 30, 2020.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2020–26727 Filed 12–3–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–337–804, A–533–813, A–560–802, A–570–851]

Certain Preserved Mushrooms From Chile, India, Indonesia, and the People's Republic of China: Final Results of Expedited Sunset Reviews of Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these sunset reviews, the Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) orders on certain preserved mushrooms (mushrooms) from Chile, India, Indonesia, and the People's Republic of China (China) would be likely to lead to a continuation or recurrence of dumping, at the levels identified in the ''Final Results of Sunset Reviews'' section of this notice.

DATES: Applicable December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Brian Smith or Kate Johnson, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–4929, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 2, 1998, and February 19, 1999, Commerce published in the **Federal Register** notices of the AD order on mushrooms from Chile and the AD orders on mushrooms from India, Indonesia, and China, respectively.[1] On August 4, 2020, Commerce published the initiation of the fourth sunset review of the *AD Orders* on mushrooms from Chile, India, Indonesia, and China, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On August 18, 2020, Commerce received timely and complete notices of intent to participate in these sunset reviews from Giorgio Foods, Inc., L.K. Bowman Co., a division of Hanover Foods Corporation, Sunny Dell Foods, LLC, and the Mushroom Company (collectively, domestic interested parties), within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic

[1] *See Notice of Antidumping Duty Order: Certain Preserved Mushrooms from Chile, 63 FR 66529 (December 2, 1998); Notice of Amendment of Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Preserved Mushrooms from India, 64 FR 8311 (February 19, 1999); Notice of Antidumping Duty Order: Certain Preserved Mushrooms from Indonesia, 64 FR 8310 (February 19, 1999); and Notice of Amendment of Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Preserved Mushrooms from the People's Republic of China, 64 FR 8308 (February 19, 1999).* The AD orders on Chile, India, Indonesia, and China are collectively referred to as *AD Orders.*

[2] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 47185 (August 4, 2020).

[3] *See* Domestic Interested Parties' Letter, ''Five-Year (''Sunset'') Review of Antidumping Duty

interested parties claimed interested party status within the meaning of section 771(9)(C) of the Act as U.S. producers in the United States of the domestic like product.[4]

On September 2, 2020, the domestic interested parties filed timely and adequate substantive responses, within the deadline specified in 19 CFR 351.218(d)(3)(i).[5] Commerce did not receive substantive responses from any respondent interested party with respect to any of the *AD Orders* covered by these sunset reviews. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted expedited (120-day) sunset reviews of the *AD Orders.*

Scope of the Orders

The merchandise covered by the *AD Orders* is certain preserved mushrooms from Chile, India, Indonesia, and China. The subject merchandise is provided for in subheadings 2003.10.0127, 2003.10.0131, 2003.10.0137, 2003.10.0143, 2003.10.0147, 2003.10.0153, and 0711.51.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope is dispositive. A full description of the scope of the *AD Orders* is contained in the accompanying Issues and Decision Memorandum.[6]

Analysis of Comments Received

A complete discussion of all issues raised in these sunset reviews, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *AD Orders* and the magnitude of the margins likely to prevail if the *AD Orders* were to be revoked, is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://enforcement.trade.gov/frn/.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Reviews

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *AD Orders* on mushrooms from Chile, India, Indonesia, and China would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average margins of up to 148.51 percent for Chile, 243.87 percent for India, 16.24 percent for Indonesia, and 198.63 percent for China.

Notification Regarding Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials, or conversion to judicial protective orders, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218 and 19 CFR 351.221(c)(5)(ii).

Dated: November 30, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the AD Orders
IV. History of the AD Orders
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Dumping Margins Likely to Prevail
VII. Final Results of Sunset Reviews
VIII. Recommendation

[FR Doc. 2020–26728 Filed 12–3–20; 8:45 am]

BILLING CODE 3510–DS–P

Orders on Certain Preserved Mushrooms from Chile, India, Indonesia, and the People's Republic of China—Domestic Interested Parties' Notice of Intent to Participate,'' dated August 18, 2020 (Intent to Participate).

[4] *See* Intent to Participate at 3.

[5] *See* Domestic Interested Party's Letters, ''Five-Year (Fourth Sunset) Review of Antidumping Duty Order on Certain Preserved Mushrooms from Chile—Domestic Interested Parties' Substantive Response to Notice of Initiation,'' dated September 2, 2020; ''Five-Year (Fourth Sunset) Review of the Antidumping Duty Order on Certain Preserved Mushrooms from India—Domestic Interested Parties' Substantive Response to Notice of Initiation,'' dated September 2, 2020; ''Five-Year (Fourth Sunset) Review of the Antidumping Duty Order on Certain Preserved Mushrooms from Indonesia—Domestic Interested Parties' Substantive Response to Notice of Initiation,'' dated September 2, 2020; and ''Five-Year (Sunset) Review of the Antidumping Duty Order on Certain Preserved Mushrooms from the People's Republic of China—Domestic Interested Parties' Substantive Response to Notice of Initiation,'' dated September 2, 2020.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Expedited Sunset Reviews of the Antidumping Duty Orders on Certain Preserved Mushrooms from Chile, India, Indonesia, and the People's Republic of China, '' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA349]

Draft 2020 Marine Mammal Stock Assessment Reports

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

ACTION: Notice; request for comments and new information.

SUMMARY: NMFS reviewed the Alaska, Atlantic, and Pacific regional marine mammal stock assessment reports (SARs) in accordance with the Marine Mammal Protection Act (MMPA). SARs for marine mammals in the Alaska, Atlantic, and Pacific regions were revised according to new information. NMFS solicits public comments on the draft 2020 SARs. NMFS is also requesting new information for strategic stocks that were not updated in 2020.

DATES: Comments must be received by March 4, 2021.

ADDRESSES: The 2020 draft SARs are available in electronic form via the internet at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports.*

Copies of the Alaska Regional SARs may be requested from Marcia Muto, Alaska Fisheries Science Center; copies of the Atlantic, Gulf of Mexico, and Caribbean Regional SARs may be requested from Elizabeth Josephson, Northeast Fisheries Science Center; and copies of the Pacific Regional SARs may be requested from Jim Carretta, Southwest Fisheries Science Center (see

FOR FURTHER INFORMATION CONTACT below).

You may submit comments or new information, identified by NOAA–NMFS–2020–0130, through the Federal e-Rulemaking Portal:

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0130.*
2. Click the ''Comment Now!'' icon, and complete the required fields.
3. Enter or attach your comments.

Instructions: NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the end of the comment period. Due to delays in processing mail related to COVID–19 and health and safety concerns, no mail, courier, or hand deliveries will be accepted. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Dr. Zachary Schakner, Office of Science and Technology, 301–427–8106, *Zachary.Schakner@noaa.gov;* Marcia Muto, 206–526–4026, *Marcia.Muto@noaa.gov,* regarding Alaska regional stock assessments; Elizabeth Josephson, 508–495–2362, *Elizabeth.Josephson@noaa.gov,* regarding Atlantic, Gulf of Mexico, and Caribbean regional stock assessments; or Jim Carretta, 858–546–7171, *Jim.Carretta@noaa.gov,* regarding Pacific regional stock assessments.

SUPPLEMENTARY INFORMATION:

Background

Section 117 of the MMPA (16 U.S.C. 1361 *et seq.*) requires NMFS and the U.S. Fish and Wildlife Service (FWS) to prepare stock assessments for each stock of marine mammals occurring in waters under the jurisdiction of the United States, including the U.S. Exclusive Economic Zone (EEZ). These reports must contain information regarding the distribution and abundance of the stock, population growth rates and trends, estimates of annual human-caused mortality and serious injury (M/SI) from all sources, descriptions of the fisheries with which the stock interacts, and the status of the stock. Initial reports were completed in 1995.

The MMPA requires NMFS and FWS to review the SARs at least annually for strategic stocks and stocks for which significant new information is available, and at least once every three years for non-strategic stocks. The term ''strategic stock'' means a marine mammal stock: (A) For which the level of direct human-caused mortality exceeds the potential biological removal level or PBR (defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population); (B) which, based on the best available scientific information, is declining and is likely to be listed as a threatened species under the Endangered Species Act (ESA) within the foreseeable future; or (C) which is listed as a threatened species or endangered species under the ESA. NMFS and FWS are required to revise a SAR if the status of the stock has changed or can be more accurately determined.

Prior to public review, the updated SARs under NMFS' jurisdiction are peer-reviewed within NMFS Fisheries Science Centers and by members of three regional independent Scientific Review Groups, established under the MMPA to independently advise NMFS on information and uncertainties related to the status of marine mammals.

The period covered by the 2020 draft SARs is 2014 through 2018. NMFS reviewed the status of all marine mammal strategic stocks as required and considered whether significant new information was available for all other stocks under NMFS' jurisdiction. As a result of this review, NMFS revised a total of 81 reports representing 84 stocks in the Alaska, Atlantic, and Pacific regions to incorporate new information. The 2020 revisions to the SARs consist primarily of updated or revised human-caused mortality and serious injury (M/SI) estimates and updated abundance estimates. For the Gulf of Maine humpback whale stock, the revisions include the application of an established capture-mark-recapture method to estimate the abundance and unobserved or cryptic mortality. Five stocks changed in status from ''non-strategic'' to ''strategic'' (Eastern Bering Sea beluga whale, Gulf of Maine humpback whale, Gulf of Mexico spinner dolphin, Gulf of Mexico striped dolphin, and Gulf of Mexico Clymene dolphin stocks). The stock summary tables have been reformatted for consistency across each region. Highlights of the draft 2020 SAR revisions are discussed below.

NMFS solicits public comments on the draft 2020 SARs. To ensure NMFS is aware of new information relevant to all strategic stocks, NMFS also requests new information for strategic stocks that were not updated in 2020. Specifically, new relevant information could include peer-reviewed information on human-caused M/SI, fishery interactions, abundance, distribution, stock structure, and habitat concerns, which could be incorporated into the SARs, and other information on emerging concerns for strategic stocks.

Alaska Reports

In 2020, NMFS reviewed new information for 28 stocks in the Alaska Region and revised 23 Stock Assessment Reports under NMFS' jurisdiction: 16 strategic stocks and 7 non-strategic stocks. The Eastern Bering Sea beluga whale stock changed from ''non-strategic'' to ''strategic'' (see below). A list of the revised stocks in 2020 for the Alaska region is presented in Table 1. Information on the remaining Alaska region stocks can be found in the final 2019 reports (Muto *et al.* 2020).

TABLE 1—LIST OF MARINE MAMMAL STOCKS IN THE ALASKA REGION REVISED IN 2020

Strategic stocks	Non-strategic stocks
• Steller sea lion, Western U.S.*	• Spotted seal, Bering.
• Northern fur seal, Eastern Pacific*	• Ribbon seal.
• Bearded seal, Beringia	• Beluga whale, Beaufort Sea.
• Ringed seal, Arctic	• Beluga whale, Eastern Chukchi Sea.*
• Beluga whale, Eastern Bering Sea*	• Beluga whale, Bristol Bay.*
• Beluga whale, Cook Inlet*	• Killer whale, Gulf of Alaska, Aleutian Islands.
• Killer whale, AT1 Transient	• Killer whale, West Coast Transient.*
• Harbor porpoise, Southeast Alaska.	
• Harbor porpoise, Gulf of Alaska.	
• Harbor porpoise, Bering Sea*.	

TABLE 1—LIST OF MARINE MAMMAL STOCKS IN THE ALASKA REGION REVISED IN 2020—Continued

Strategic stocks	Non-strategic stocks
• Sperm whale, North Pacific. • Humpback whale, Western North Pacific. • Humpback whale, Central North Pacific. • Fin whale, Northeast Pacific. • North Pacific right whale, Eastern North Pacific. • Bowhead whale, Western Arctic.	

* Includes updated abundance estimates.

Stock Name Changes

NMFS changed the stock names for the four ice seal stocks (bearded seal, ribbon seal, ringed seal, and spotted seal) to reflect advice in the NMFS Policy Directive, ''Guidelines for preparing stock assessment reports pursuant to the 1994 amendments to the Marine Mammal Protection Act'' (NMFS 2016) regarding trans-boundary stocks. While the stocks extend beyond the boundaries of the U.S. EEZ, the stock assessment reports consider only the portions of the stocks that are within the U.S. EEZ because the relevant stock assessment data on abundance and human-caused mortality and serious injury are generally not available for the broader range of the stock or even for waters adjacent to the U.S. EEZ.

Beluga Whale, Eastern Bering Sea

The updated abundance estimate, derived from aerial surveys in 2017, is 9,242 beluga whales. This is an increase from the previous estimate of 6,994. The updated minimum population estimate is 8,357, previously considered unreliable for calculating a PBR as the survey data were more than eight years old. The Eastern Bering Sea beluga whale stock changed from non-strategic to strategic because the calculated PBR of 167 is less than the estimated human-caused mortality and serious injury of 198 beluga whales.

Beluga Whales—Cook Inlet

A new approach using video data was applied to address bias in the group-size estimation process of previous methods. The updated best estimate of abundance in 2018, derived using this new analytical method on aerial survey data from 2014, 2016, and 2018, is 279 beluga whales. This is a decrease from the previous estimate of 327. During the most recent 10-year time period (2008–2018), the estimated exponential trend in the abundance estimates is a decline of 2.3 percent per year (95 percent Probability Interval: –4.1 percent to –0.6 percent), with a 99.7 percent probability of a decline, and a 93.0 percent probability of a decline that is more than 1 percent per year (Wade *et al.* 2019).

Harbor Porpoise, Bering Sea

The abundance estimate for harbor porpoise in the eastern Bering Sea, derived from vessel surveys in association with pollock stock assessment surveys in 2008, is 5,713 harbor porpoise. However, this estimate is for only a small portion of the range of this stock. Because the survey data are more than eight years old, the minimum population estimate (N_{MIN}) is now considered unknown, and the PBR is now considered undetermined.

Atlantic Reports

In 2020, NMFS reviewed all 116 stocks in the Atlantic region for new information (including the Atlantic Ocean, Gulf of Mexico, and U.S. territories in the Caribbean). This year, NMFS revised 33 reports in the Atlantic region (13 strategic and 20 non-strategic). Four stocks (Gulf of Maine humpback whale, Gulf of Mexico spinner dolphin, Gulf of Mexico striped dolphin, and Gulf of Mexico Clymene dolphin) changed from ''non-strategic'' to ''strategic'' (see below). A list of the revised stocks in the Atlantic region for 2020 is presented in Table 2. Information on the remaining Atlantic region stocks can be found in the final 2019 reports (Hayes *et al.* 2020).

TABLE 2—LIST OF MARINE MAMMAL STOCKS IN THE ATLANTIC REGION REVISED IN 2020

Strategic stocks	Non-strategic stocks
• North Atlantic right whale, Western North Atlantic (WNA) * ..... • Fin whale, WNA * ..... • Sei whale, Nova Scotia ..... • Humpback whale, Gulf of Maine ..... • Common bottlenose dolphin, WNA Northern Migratory coastal ..... • Common bottlenose dolphin, WNA Southern Migratory coastal ..... • Common bottlenose, Northern North Carolina Estuarine System ..... • Common bottlenose, Southern North Carolina Estuarine System ..... • Bryde's whale, Gulf of Mexico * ..... • Clymene dolphin, Gulf of Mexico * ..... • Sperm whale, Gulf of Mexico * ..... • Spinner dolphin, Gulf of Mexico * ..... • Striped dolphin, Gulf of Mexico*	• Minke whale, Canadian East Coast.* • Common dolphin, WNA.* • Harbor porpoise, Gulf of Maine. • Gray seal, WNA. • Blainville's beaked whale, Gulf of Mexico.* • Cuvier's beaked whale, Gulf of Mexico.* • Gervais' beaked whale, Gulf of Mexico.* • Bottlenose dolphin, Gulf of Mexico, Oceanic.* • Dwarf sperm whale, Gulf of Mexico.* • Pygmy sperm whale, Gulf of Mexico.* • False killer whale, Gulf of Mexico.* • Fraser's dolphin, Gulf of Mexico.* • Killer whale, Gulf of Mexico.* • Harbor seal, WNA. • Pantropical spotted dolphin, Gulf of Mexico.* • Pygmy killer whale, Gulf of Mexico.* • Risso's dolphin, Gulf of Mexico.* • Rough-toothed dolphin, Gulf of Mexico.* • Short-finned pilot whale, Gulf of Mexico.* • Melon-headed whale, Gulf of Mexico.*

* Includes updated abundance estimates.

North Atlantic Right Whale, Western Atlantic

For the second year, western North Atlantic right whale stock size is based on a state-space model of the sighting histories of individual whales (Pace *et al.* 2017). Using a hierarchical, state-space Bayesian open population model of these histories produced a median abundance value of 412 individuals (95 percent credible intervals 403–424). The previous best abundance estimate in the 2019 SAR was 428 (95 percent credible intervals 406–447).

The estimated annual rate of total mortality using this modeling approach is 18.6 animals for the period 2013–2017 (Pace *et al.* submitted). This estimated total mortality accounts for detected mortality and serious injury, as well as undetected (unobserved or cryptic) mortality within the population. When comparing the detected mortality and serious injury to the model estimates for the five-year period (2013–2017), the detection rate was 51 percent of the state space model's annual morality estimate.

Humpback Whale, Gulf of Maine

For the Gulf of Maine humpback whale report, two independent abundance estimates are presented. One based on ship/aerial line-transect surveys, and a second based on applying mark and recapture methods to photo identification records (Robbins and Pace 2018). The best abundance estimate of 1,396 (95 percent credible intervals 1363–1429) is based on the mark and recapture method that utilizes a state-space model of the sighting histories of individual whales. Using the resulting N_{MIN} associated with this abundance estimate of 1,380, the PBR for the Gulf of Maine Humpback whale stock is 22.

The state-space model was also used to estimate total mortality as described above for North Atlantic right whales. The estimated annual rate of total mortality using this modeling method is 57.6 animals for the period 2011–2015 (estimated mortality for 2016 forward is not yet available due to ongoing processing of all photographs collected through 2020). The estimated human caused mortality and serious injury now exceeds PBR (22), and the Gulf of Maine humpback whale stock changed in status from ''non-strategic'' to ''strategic.''

Gulf of Mexico Stocks Abundance Estimates

New abundance estimates for 20 Gulf of Mexico stocks were generated from vessel surveys conducted in the northern Gulf of Mexico and an updated methodology (Garrison *et al.* 2020). The new estimates were produced using a new double-platform data-collection procedure to allow estimation of the detection probability on the trackline using the independent observer approach assuming point independence (Laake and Borchers 2004). Unlike previous abundance estimates, these estimates were corrected for the probability of detection on the trackline. Three stocks changed from ''non-strategic'' to ''strategic'' (spinner dolphin, striped dolphin, and Clymene dolphin) because the mean modeled annual human-caused mortality and serious injury due to the Deepwater Horizon (DWH) oil spill exceeds PBR.

Deep Water Horizon Mortality and Serious Injury Estimates

A population model was developed to estimate the injury and time to recovery for stocks affected by the DWH oil spill, taking into account long-term effects resulting from mortality, reproductive failure, reduced survival rates, and the proportion of the stock exposed to DWH oil (DWH MMIQT 2015). As a result, the mean modeled annual human-caused mortality and serious injury due to the DWH oil spill now exceeds PBR in Gulf of Mexico spinner dolphin, striped dolphin, and Clymene dolphin stocks. The mortality is not associated with commercial fishery-related mortality and serious injury and does not trigger action under section 118 of the MMPA.

Common Bottlenose Dolphin, Western North Atlantic Stocks

An analysis of coast-wide (New Jersey to Florida) trends in abundance for common bottlenose dolphins was included in the WNA Northern and Southern Migratory Coastal SARs and indicated a declining trend. There was a statistically significant change in slope between 2011 and 2016, indicating a decline in population size. The coast-wide inverse-variance weighted average estimate for coastal common bottlenose dolphins during 2011 was 41,456 (Coefficient of Variation—CV = 0.30), while the estimate during 2016 was 19,470 (CV = 0.23; Garrison *et al.* 2017). This apparent decline in common bottlenose dolphin abundance in coastal waters along the eastern seaboard may be a result of the 2013–2015 Unusual Mortality Event.

Pacific Reports

In 2020, NMFS reviewed all 85 stocks in the Pacific region (waters along the west coast of the United States, within waters surrounding the main and Northwestern Hawaiian Islands, and within waters surrounding U.S. territories in the Western Pacific) for new information, and revised SARs for 28 stocks (7 strategic and 21 non-strategic). A list revised stocks in 2020 for the Pacific region is presented in Table 3. Information on the remaining Pacific region stocks can be found in the final 2019 reports (Carretta *et al.* 2020).

TABLE 3—LIST OF MARINE MAMMAL STOCKS IN THE PACIFIC REGION REVISED IN 2020

Strategic stocks	Non-strategic stocks
• False killer whale, Main Hawaiian Islands Insular	• Gray whale, Eastern North Pacific.
• Hawaiian monk seal *	• Rough-toothed dolphin, Hawaii.*
• Killer whale, Eastern N Pacific Southern * Resident	• Risso's dolphin, Hawaii.*
• Sperm whale, Hawaii *	• Pantropical spotted dolphin, Hawaii Pelagic.*
• Fin whale, Hawaii *	• Bottlenose dolphin, Hawaii Pelagic.*
• Fin whale, California/Oregon/Washington	• Striped dolphin, Hawaii Pelagic.*
• Gray whale, Western North Pacific	• Frasers dolphin, Hawaii.*
	• Melon-headed whale.*
	○ Hawaiian islands.
	○ Kohala Resident.
	• Pygmy killer whale, Hawaii.*
	• False Killer whale.*
	○ Northwest Hawaiian Islands.
	○ Hawaii Pelagic.
	• Killer whale, Hawaii.*
	• Short-finned pilot whale, Hawaii.*
	• Blainville's beaked whale, Hawaii Pelagic.*

TABLE 3—LIST OF MARINE MAMMAL STOCKS IN THE PACIFIC REGION REVISED IN 2020—Continued

Strategic stocks	Non-strategic stocks
	• Cuvier's beaked whale, Hawaii Pelagic.* • Longman's beaked whale, Hawaii.* • Pygmy sperm whale, Hawaii.* • Dwarf sperm whale, Hawaii. • Bryde's whale, Hawaii.* • Minke whale, Hawaii.*

* Includes updated abundance estimates.

Updated Abundance Estimates for Hawaiian Stocks

The majority of Hawaii reports contain new abundance estimates for all Hawaiian Islands Cetacean Assessment Survey (HICEAS) years (2002, 2010, and 2017) using a consistent analysis approach across years. Some stocks use model-based estimates of abundance when available.

False Killer Whale, All Pacific Stocks

The stock range and boundaries of the three Hawaiian stocks of false killer whales were recently reevaluated, given significant new information on the occurrence and movements of each stock in Bradford *et al.* (2015), and further revised for the pelagic stock in Bradford *et al.* (2020). A new model-based methodology, taking into account the removal of the inner stock boundary for the pelagic stock, was used to estimate abundance. This resulted in new abundance, N_{MIN}, and PBR estimates for the Hawaii EEZ and broader central Pacific study area.

Common Bottlenose Dolphin-Hawaii Pelagic

There were no sightings of bottlenose dolphins during systematic survey effort in 2017, and therefore design-based estimates are not available. This results in an undetermined abundance estimate (previously 21,815) and correspondingly, the PBR for this population is now undetermined (previously 140).

References

Bradford, A.L., E.M. Oleson, R.W. Baird, C.H. Boggs, K.A. Forney, and N.C. Young. 2015. Revised stock boundaries for false killer whales (*Pseudorca crassidens*) in Hawaiian waters. U.S. Department of Commerce, NOAA Technical Memorandum. NOAA–TM–NMFS–PIFSC–47, 29 p.

Bradford, A.L., E.A. Becker, E.M. Oleson, K.A. Forney, J.E. Moore, and J. Barlow. 2020. Abundance estimates of false killer whales in Hawaiian waters and the broader central Pacific. U.S. Department of Commerce, NOAA Technical Memorandum NOAA–TM–NMFS–PIFSC–104, 78 p.

Carretta, J.V., K.A. Forney, E.M. Oleson, D.W. Weller, A.R. Lang, J. Baker, M.M. Muto, B. Hanson, A.J. Orr, H. Huber, M.S. Lowry, J. Barlow, J.E. Moore, D. Lynch, L. Carswell, and R.L. Brownell Jr. 2020. U.S. Pacific marine mammal stock assessments: 2019. U.S. Department of Commerce, NOAA Technical Memorandum NMFS–SWFSC–629, 385 p.

DWH MMIQT. 2015. Models and analyses for the quantification of injury to Gulf of Mexico cetaceans from the *Deepwater Horizon* Oil Spill, MM_TR.01_Schwacke_Quantification.of.Injury.to.GOM.Cetaceans. Southeast Fisheries Science Center Reference Document PRBD–2020–02.

Garrison, L.P., J. Ortega-Ortiz, and G. Rappucci. 2020. Abundance of marine mammals in the waters of the U.S. Gulf of Mexico in the summer of 2017 and 2018. Southeast Fisheries Science Center Reference Document PRBD–2020–07, 55 p.

Garrison, L.P., K. Barry, and W. Hoggard. 2017. The abundance of coastal morphotype bottlenose dolphins on the U.S. east coast: 2002–2016. Southeast Fisheries Science Center Reference Document PRBD–2017–01, 43 p.

Hayes, S.A., E. Josephson, K. Maze-Foley, and P.E. Rosel, Editors. 2020. U.S. Atlantic and Gulf of Mexico marine mammal stock assessments—2019. U.S. Department of Commerce, NOAA Technical Memorandum NMFS–NE–264, 477 p.

Laake, J.L. and D.L. Borchers. 2004. Methods for incomplete detection at distance zero, In: Advanced distance sampling, edited by S.T. Buckland, D.R. Andersen, K.P. Burnham, J.L. Laake, and L. Thomas, p. 108–189, Oxford University Press, New York.

Muto, M.M., V.T. Helker, B.J. Delean, R.P. Angliss, P.L. Boveng, J.M. Breiwick, B.M. Brost, M.F. Cameron, P.J. Clapham, S.P. Dahle, M.E. Dahlheim, B.S. Fadely, M.C. Ferguson, L.W. Fritz, R.C. Hobbs, Y.V. Ivashchenko, A.S. Kennedy, J.M. London, S.A. Mizroch, R.R. Ream, E.L. Richmond, K.E.W. Shelden, K.L. Sweeney, R.G. Towell, P.R. Wade, J.M. Waite, and A.N. Zerbini. 2020. Alaska marine mammal stock assessments, 2019. U.S. Department of Commerce, NOAA Technical Memorandum NMFS–AFSC–404, 395 p.

National Marine Fisheries Service (NMFS). 2016. Guidelines for preparing stock assessment reports pursuant to the 1994 amendments to the Marine Mammal Protection Act, 23 p.

Pace, R.M., III, P.J. Corkeron, and S.D. Kraus. 2017. State-space mark-recapture estimates reveal a recent decline in abundance of North Atlantic right whales. Ecol. and Evol. 7:8730–8741. DOI: 10.1002/ece3.3406.

Pace, R.M., III, R. Williams, A.R. Knowlton, H.M. Pettis, and S.D. Kraus. Submitted. Cryptic mortality of North Atlantic right whales.

Robbins, J. and R.M. Pace, III. 2018. Trends in abundance of North Atlantic humpback whales in the Gulf of Maine. EE133F–17–SE–1320 Task I Contract Report. Northeast Fisheries Science Center, Woods Hole, MA.

Wade, P.R., C. Boyd, K.E.W. Shelden, and C.L. Sims. 2019. Chapter 2: Group size estimates and revised abundance estimates and trend for the Cook Inlet beluga population. In K.E.W. Shelden and P.R. Wade (eds.), Aerial surveys, distribution, abundance, and trend of belugas (*Delphinapterus leucas*) in Cook Inlet, Alaska, June 2018. AFSC Processed Rep. 2019–09, 93 p. Alaska Fisheries Science Center, Seattle, WA.

Dated: November 30, 2020.

Christopher Wayne Oliver,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–26681 Filed 12–3–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; West Coast Groundfish Trawl Economic Data

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on

proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before February 2, 2021.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *Adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0618 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Erin Steiner, Northwest Fisheries Science Center, 2725 Montlake Blvd. E, Seattle, WA 98103, (206) 860–3202 or *erin.steiner@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a renewal of a currently approved information collection.

This information collection is needed in order to meet the monitoring requirements of the Magnuson-Stevens Act (MSA). An Individual Fishing Quota (IFQ) Program for the West Coast groundfish trawl fishery was implemented in January 2011 by the Pacific Fisheries Management Council. This mandatory data collection program will continue to collect economic cost earnings data from all harvesters and processors participating in the West Coast groundfish trawl fishery.

Data will be collected from all catcher vessels registered to a limited entry trawl endorsed permit, quota share permit owners, catcher processors registered to catcher processor permits, and motherships registered to mothership permits, first receivers, and shore-based processors that received round or head-and-gutted IFQ groundfish or whiting from a first receiver to provide the necessary information for analyzing the effects of the West Coast Groundfish Trawl Catch Share Program. As stated in 50 CFR 660.114, the Economic Data Collection (EDC) forms due on September 1, 2020, will provide data for the 2019 operating year. Northwest Fishery Science Center (NWFSC) economists will use these data to examine how the implementation of catch share management affects fleet structure, production costs, employment, generation and distribution of economic rent, and regional economic impacts. Analysis based on this data will not only be used for providing information to the Pacific Fisheries Management Council on changes to the catch share program, but also to meet monitoring requirements for catch share programs in the Magnuson-Stevens Act.

II. Method of Collection

Vessel, first receiver and shore-based processor forms may be submitted via mail or electronically. All quota share owner survey forms must be submitted online as part of the quota share permit renewal system.

III. Data

OMB Control Number: 0648–0618.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for-profit and not-for-profit organization.

Estimated Number of Respondents: 349.

Estimated Time per Response: 8 hours for catcher processors, catcher vessels, and motherships, 1 hour for quota share permit owners, and 20 hours for first receivers and shore-based processors.

Estimated Total Annual Burden Hours: 1,975.

Estimated Total Annual Cost to Public: $0 in recordkeeping/reporting costs.

Respondent's Obligation: Mandatory.

Legal Authority: 50 CFR 660.114.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

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 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.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–26688 Filed 12–3–20; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date deleted from the Procurement List:* January 03, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 10/30/2020, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities.

The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following service(s) are deleted from the Procurement List:

Service(s)

Service Type: Data Entry/Telephone.
Mandatory for: GSA, FAS, Heartland Acquisition Center, Integrated Facilities Management & Industrial Products Solutions Center, Kansas City, MO.
Designated Source of Supply: JobOne, Independence, MO.
Contracting Activity: FEDERAL ACQUISITION SERVICE, GSA/FAS TOOLS ACQUISITION DIVISION.

Service Type: Janitorial/Custodial.
Mandatory for: GSA, Parking Lot Bismark: 1st and Thayer Streets, Bismarck, ND.
Mandatory for: GSA, Storage Building: 117 Main Street, Bismarck, ND.
Designated Source of Supply: Pride, Inc., Bismarck, ND.
Contracting Activity: PUBLIC BUILDINGS SERVICE, PBS R8.

Service Type: Custodial Services.
Mandatory for: Department of Veterans Affairs, Community Based Outpatient Clinic, 225 Boston Road, Lynn, MA.
Mandatory for: Department of Veterans Affairs, Community Based Outpatient Clinic, 108 Merrimack Street, Haverhill, MA.
Designated Source of Supply: Morgan Memorial Goodwill Industries, Boston, MA.
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 241–NETWORK CONTRACT OFFICE 01.

Service Type: Installation Support Services.
Mandatory for: US Army, Fort Hood, Fort Hood, TX.
Designated Source of Supply: Training, Rehabilitation, & Development Institute, Inc., San Antonio, TX.
Contracting Activity: DEPT OF THE ARMY, W6QM MICC–FDO FT HOOD.

Service Type: Janitorial/Custodial.
Mandatory for: Internal Revenue Service: 11501 and 11601 Roosevelt Boulevard, Philadelphia, PA.
Contracting Activity: INTERNAL REVENUE SERVICE, DEPT OF TREAS, IRS, OFC OF PROCUREMENT OPERATIONS.

Service Type: Mailroom Operation.
Mandatory for: GSA, Arlington: Crystal Mall #3, Arlington, VA.
Designated Source of Supply: Didlake, Inc., Manassas, VA.
Contracting Activity: OFFICE OF THE ADMINISTRATOR (ACMD), THE INTERNAL ACQUISITION DIVISION (IAD).

Service Type: Janitorial/Custodial.
Mandatory for: Denver Federal Center: Buildings 76, 80, 93 and 94, Denver, CO.
Mandatory for: Denver Federal Center: Building 75, 80 (+3 adjacent trailers), 82, 83K, 85, 710, 710A and 810, Denver, CO.
Designated Source of Supply: North Metro Community Services for Developmentally Disabled, Westminster, CO.
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FPDS AGENCY COORDINATOR.

Michael R. Jurkowski,
Deputy Director, Business & PL Operations.

[FR Doc. 2020–26735 Filed 12–3–20; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add product(s) and service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) previously furnished by such agencies.

DATES: Comments must be received on or before: January 03, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product(s) and service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities. The following product(s) and service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product(s)

NSN(s)—Product Name(s):
890008303S—Vegetarian Burrito With Chips and Drink
890008311S—Cold Vegetarian Sandwich With Chips and Drink
890008312S—Vegetarian Cheeseburger Meal With Chips and Drink
890008300S—Breakfast Burrito and Drink
890008301S—Cold Sandwich With Chips and Drink
890008302S—Dinner Burrito With Fruit Cup and Drink
890008304S—Cheeseburger Meal With Chips and Drink
890008306S—Chicken Teriyaki Bowl and Drink
890008307S—Snack
890008305S—Chicken Salad With Chip and Drink
890008309S—Milk, 8 oz. box
890008308S—Water, 16.9 oz. bottle
890008310S—Juice, 6 oz. box
Designated Source of Supply: ARC-Imperial Valley, El Centro, CA
Contracting Activity: U.S. CUSTOMS AND BORDER PROTECTION, BORDER ENFORCEMENT CTR DIV

Service(s)

Service Type: Facility Support Services
Mandatory for: National Park Service, National Capital Area, Multiple Locations, Washington, DC
Designated Source of Supply: Portco, Inc., Portsmouth, VA
Contracting Activity: NATIONAL PARK SERVICE, NCR REGIONAL CONTRACTING (30000)

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
5340–00–479–2949—Strap, Webbing, 57″ x 1″
5340–00–543–3271—Strap, Webbing, 9–3/4″ x 1″
5340–00–753–3740—Strap, Webbing, 8″ x 1″
Designated Source of Supply: The Charles Lea Center, Inc., Spartanburg, SC
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

Michael R. Jurkowski,
Deputy Director, Business & PL Operations.

[FR Doc. 2020–26736 Filed 12–3–20; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 9:30 a.m. EST, Tuesday, December 8, 2020.

PLACE: Virtual meeting.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') will hold this meeting to consider the following matters:

- Final Rule: Electronic Trading Risk Principles;
- Final Rule: Swap Execution Facilities (Audit Trail, Financial Resources, and CCO Requirements);
- Final Rule: Exemptions from Swap Trade Execution Requirement;
- Withdrawal of Unadopted Proposals in the 2018 SEF Proposed Rule: Swap Execution Facilities and Trade Execution Requirement;
- Final Rule: Part 190 Bankruptcy Regulations;
- Final Rule: Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants (Minimum Transfer Amount);
- Final Rule: Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants (Material Swap Exposure Definition and Initial Margin Calculation); and
- Final Rule: Revision of Certain Regulatory Provisions to Incorporate Changes in the Commission's Administrative Structure.

The agenda for this meeting will be available to the public and posted on the Commission's website at *https://www.cftc.gov.* Instructions for public access to the live feed of the meeting will also be posted on the Commission's website. In the event that the time, date, or place of this meeting changes, an announcement of the change, along with the new time, date, or place of the meeting, will be posted on the Commission's website.

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, Secretary of the Commission, 202–418–5964.

Authority: 5 U.S.C. 552b.

Dated: December 1, 2020.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2020–26791 Filed 12–2–20; 11:15 am]

BILLING CODE 6351–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0038]

High School and Beyond 2021 (HS&B:21) Base-Year Full-Scale Study Data Collection; Correction

AGENCY: Institute for Education Sciences, National Center for Education Statistics (IES/NCES), Department of Education (ED).

ACTION: Correction notice.

SUMMARY: The PRA Coordinator, Strategic Collections and Clearance, Office of the Chief Data Officer, Office of Planning, Evaluation and Policy Development, hereby issues a correction notice as required by the Paperwork Reduction Act of 1995.

SUPPLEMENTARY INFORMATION: On November 30, 2020, the U.S. Department of Education published a 30-day comment period notice in the **Federal Register** with FR DOC# 2020–26269 (Page 76545, Column 2, Column 3; Page 76546, Column 1) seeking public comment for an information collection entitled, ''High School and Beyond 2021 (HS&B:21) Base-Year Full-Scale Study Data Collection''. The tile is incorrect. The title should be High School and Beyond 2022 (HS&B:22) Base-Year Full-Scale Data Collection Year Delay Change Request. The abstract is incorrect. The correct abstract should read as follows.

The High School and Beyond 2022 study (HS&B:22) will be the sixth in a series of longitudinal studies at the high school level conducted by the National Center for Education Statistics (NCES), within the Institute of Education Sciences (IES) of the U.S. Department of Education. HS&B:22 will follow a nationally representative sample of ninth grade students from the start of high school in the fall of 2022 to the spring of 2026 when most will be in twelfth grade. A field test will be conducted one year prior to the full-scale study. The study sample will be freshened in 2026 to create a nationally representative sample of twelfth-grade students. A high school transcript collection and additional follow-up data collections beyond high school are also planned. In preparation for the HS&B:20 Base-Year Full-Scale study (BYFS), originally scheduled to take place in the fall of 2020, the Office of Management and Budget (OMB) approved (OMB #1850–0944 v.1–5) requests to conduct the HS&B:20 Base-Year Field Test (BYFT) and the BYFS sampling and state, school district, school, and parent recruitment activities, both of which began in the fall of 2019. These activities include collecting student rosters and selecting the BYFS sample. BYFT activities ended in December 2019. A 60-day review of the full Base-Year Full-Scale Data Collection package was completed between February and April 2020. In the middle of that 60-day review, due to the COVID–19 pandemic, NCES decided to postpone this collection for one year, to Fall 2021, and updated the study documentation appropriately for the 30-day review. OMB provided approval to the new package, with the 2021 schedule, in October 2020 (OMB #1850–0944 v.7). Due to continued burden on schools due to the ongoing COVID–19 pandemic, NCES has decided to further delay the BYFS study data collection to Fall 2022. This submission addresses that delay and amends the previously approved package to update it with these new plans.

This submission includes all pieces of the High School and Beyond 2022 (HS&B:22) Base-Year Full-Scale Study Data Collection package. The primary purpose of this change request is to add new communication materials to immediately send to states, schools, and districts that have already agreed to participate in the HS&B Main Study, notifying those interested parties of the additional one-year delay. This request does not affect the approved total cost to the federal government for conducting this study nor the estimated respondent burden.

Dated: December 1, 2020.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Office of the Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–26705 Filed 12–3–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for OMB review and comment.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its Semi-Annual Davis-Bacon Enforcement Report, OMB Control Number 1910–5165. All Federal agencies administering programs subject to Davis-Bacon wage provisions are required by to submit a report of all new

covered contracts/projects and all compliance and enforcement activities every six months to the Department of Labor (DOL). In order for DOE to comply with this reporting requirement, it must collect contract and enforcement information from the Recovery Act funded Loan Borrowers, Loan Guarantee Borrowers, DOE direct contractors, and other prime contractors that administer DOE programs subject to Davis-Bacon requirements. DOE will require that such entities complete and submit a Semi-Annual Enforcement Report every six months, by the 21st of April and the 21st of October each year.

DATES: Comments regarding this collection must be received on or before February 2, 2021. 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, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4718.

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 instrument and instructions should be directed to:

John M. Sullivan, Attorney-Advisor (Labor), GC–63, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, or by fax at (202) 586–0971 or by email to *john.m.sullivan@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) *OMB No.:* 1910–5165; (2) *Information Collection Request Title:* Davis-Bacon Semi-Annual Enforcement Report; (3) *Type of Request:* Renewal; (4) *Purpose:* This information collection ensures Departmental compliance with 29 CFR 5.7(b). The respondents are Department of Energy M&O, Facilities Management Contractors, and recipients of financial assistance whose work is subject to the Davis-Bacon Act and Davis-Bacon Related Acts; (5) *Annual Estimated Number of Respondents:* 75; (6) *Annual Estimated Number of Total Responses:* 150; (7) *Annual Estimated Number of Burden Hours:* 2 per respondent annually, for a total of 300 per year; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $103.00 per respondent.

Statutory Authority: 29 CFR 5.7(b).

Signing Authority

This document of the Department of Energy was signed on December 1, 2020, by John T. Lucas, Deputy General Counsel for Transactions, Technology and Contractor Human Resources, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on December 1, 2020.

Treena V. Garrett,

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

[FR Doc. 2020–26732 Filed 12–3–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–13–000]

Californians for Green Nuclear Power, Inc. v. North American Electric Reliability Corporation, Western Electricity Coordinating Council, California Independent System Operator Corporation, California Public Utilities Commission California State Water Resources Control Board, California State Lands Commission; Notice of Amended Complaint

Take notice that on November 25, 2020, pursuant to the Federal Power Act, the Natural Gas Act of 1938, the Federal Pipeline Safety Regulations,[1] and section 206 of the Rules of Practice and Procedure of the Federal Energy Regulatory Commission,[2] Californians for Green Nuclear Power, Inc. (Complainant) filed an amended complaint, amending its October 26, 2020 formal complaint against North American Electric Reliability Corporation, Western Electricity Coordinating Council, California Independent System Operator Corporation, California Public Utilities Commission, California State Water Resources Control Board, and California State Lands Commission, (Respondent) alleging that, Respondents failed to properly analyze the bulk electric system and bulk natural gas system consequences in light of certain California-specific hazards in connection with the approval of the voluntary plan to close Diablo Canyon Power Plant in 2025, all as more fully explained in the complaint.

The Complainant certifies that copies of the complaint were served on the contacts listed for Respondents in the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

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.

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

[1] The Federal Power Act, 16 U.S.C. 791 *et seq.,* the Energy Policy Act of 2005, 42 U.S.C. 13201 *et seq.* (2005), the Natural Gas Act of 1938 15 U.S.C. 717(b) *et seq.,* and Federal Pipeline Safety Regulations, 49 CFR 192 (2020).

[2] 18 CFR 385.206 (2020).

assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov,* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on December 15, 2020.

Dated: November 30, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26711 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2530–057]

Brookfield White Pine Hydro LLC; Notice of Application Tendered for Filing With the Commission and Establishing Procedural Schedule for Licensing and 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.:* 2530–057.

c. *Date Filed:* November 20, 2020.

d. *Applicant:* Brookfield White Pine Hydro LLC (White Pine Hydro).

e. *Name of Project:* Hiram Hydroelectric Project.

f. *Location:* The existing project is located on the Saco River in the towns of Hiram, Baldwin, Brownfield, and Denmark within Oxford and Cumberland Counties, Maine. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)-825(r).

h. *Applicant Contact:* Luke Anderson, Licensing Manager, Brookfield White Pine Hydro LLC, 150 Main Street, Lewiston, ME 04240; Telephone (207) 755–5600.

i. *FERC Contact:* Dianne Rodman, (202) 502–6077 or *dianne.rodman@ferc.gov.*

j. This application is not ready for environmental analysis at this time.

k. Project *Description:* The existing Hiram Project consists of a 255-acre, 7.5-mile-long impoundment at normal full pond elevation 349.0 feet; a 448-foot-long dam located at the top of Great Falls fitted with an inflatable dam across the spillway crest; an intake that is integral to the dam; a 320-foot-long, 15.5-foot-diameter penstock that bifurcates to one 170-foot-long by 10-foot-wide penstock (to Unit 1), and one 80-foot-long by 15.5-foot-diameter penstock (to Unit 2); a powerhouse containing two turbine-generator units, Unit 1 rated at 2.4 megawatts (MW) and Unit 2 at 8.1 MW, for a total installed capacity of 10.5 MW; and appurtenant facilities. The project's transmission facilities include: (1) Generator leads; (2) a substation located adjacent to, and north of, the powerhouse; and (3) a transmission circuit connecting the substation to a non-project switching station. The project generates an annual average of 45,142 megawatt-hours.

White Pine Hydro proposes to continue to: operate the project in a run-of-river mode from October 1 through November 15, with head pond drawdowns limited to 1 foot or less from the full pond elevation, or from the spillway crest when the inflatable dam is down. From November 16 through September 30, White Pine Hydro proposes to continue to cycle daily operations whereby it would turn on and off its generating units when inflow is sufficient to meet load demands, resulting in drawdown of the head pond by up to 2 feet from the full pond elevation during normal project operation, or from the spillway crest when the inflatable dam is down. During this period, White Pine Hydro would continue to provide a minimum flow of 300 cubic feet per second (cfs), of inflow, whichever is less below the powerhouse.

White Pine Hydro proposes to remove from the current project boundary 152 acres of land and 25 acres of water.

l. In addition to publishing the full text of this notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this notice, as well as other documents in the proceeding (*e.g.,* license application) via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document (P–2530). 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, (866) 208–3676 or (202) 502–8659 (TTY).

m. You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Procedural Schedule:

The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target Date
Notice of Acceptance/ Notice of Ready for Environmental Analysis.	January 2021.
Filing of recommendations, preliminary terms and conditions, and fishway prescriptions.	March 2021.
Reply Comments due ..	May 2021.

o. 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: November 30, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26712 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3251–010]

Cornell University; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a new license for the Cornell University Hydroelectric Project, located on Fall Creek in the City of Ithaca, Tompkins County, New York, and has prepared an Environmental Assessment (EA) for the project. The project does not occupy federal land.

The EA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA via the internet through the Commission's Home Page (*http://www.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 Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/eSubscription.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 45 days from the date of this notice.

The Commission strongly encourages electronic filings. Please file comments using the Commission's eFiling system at *https://ferconline.ferc.gov/eFiling.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–3251–010.

For further information, contact Chris Millard at (202) 502–8256 or by email at *christopher.millard@ferc.gov.*

Dated: November 30, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26713 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC21–29–000.
Applicants: Basin Electric Power Cooperative, Inc.
Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Basin Electric Power Cooperative.
Filed Date: 11/25/20.
Accession Number: 20201125–5167.
Comments Due: 5 p.m. ET 12/16/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1818–024; ER10–1819–027; ER10–1820–030.
Applicants: Public Service Company of Colorado, Northern States Power Company, a Minnesota corporation, Northern States Power Company, a Wisconsin corporation.
Description: Notice of Change in Status of Public Service Company of Colorado, et al.
Filed Date: 11/25/20.
Accession Number: 20201125–5195.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER10–2531–011.
Applicants: Cedar Creek Wind Energy, LLC.
Description: Notice of Non-Material Change in Status of Cedar Creek Wind Energy, LLC.
Filed Date: 11/25/20.
Accession Number: 20201125–5194.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER20–1736–002.
Applicants: Versant Power.
Description: Compliance filing: Order No. 864 Compliance Filing—Response to Staff Letter (ER20–1736–____) to be effective N/A.
Filed Date: 11/25/20.
Accession Number: 20201125–5001.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER20–1739–001.
Applicants: American Transmission Systems, Incorporated, PJM Interconnection, L.L.C.
Description: Compliance filing: ATSI Response to Deficiency Letter for Order No. 864 Compliance to be effective N/A.
Filed Date: 11/25/20.
Accession Number: 20201125–5013.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–116–001.
Applicants: XO Energy CAL, LP.
Description: Tariff Amendment: Amendment to 1 to be effective 10/16/2020.
Filed Date: 11/25/20.
Accession Number: 20201125–5152.
Comments Due: 5 p.m. ET 12/16/20.

Docket Numbers: ER21–496–000.
Applicants: ISO New England Inc., New England Power Pool.
Description: ISO New England Inc. submits Installed Capacity Requirement, Hydro Quebec Interconnection Capability Credits and Related Values for the 2021–2022, 2022–2023 and 2023–2024 Annual Reconfiguration Auctions.
Filed Date: 11/25/20.
Accession Number: 20201125–5179.
Comments Due: 5 p.m. ET 12/16/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by 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: November 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26708 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–12–000]

Mountain Valley Pipeline, LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on November 18, 2020, Mountain Valley Pipeline, LLC (Mountain Valley), 2200 Energy Drive Canonsburg, Pennsylvania 15317, filed an application under section 7(c) of the Natural Gas Act (NGA), and Part 157 of the Commission's regulations requesting authorization to amend Mountain Valley's existing certificate of public convenience and necessity (Certificate) for the Mountain Valley Pipeline Project

(Project).[1] Mountain Valley requests that the Commission amend the Certificate to grant Mountain Valley the ability to complete construction of the Project between Mileposts 0 and 77 by crossing all remaining applicable wetlands and waterbodies using conventional bores. In addition, Mountain Valley requests approval of a minor shift in the permanent right-of-way to entirely avoid one wetland (A–002 at Milepost 0.70). Mountain Valley states that amending its Certificate to use 41 conventional bores to cross 69 waterbodies and wetlands that the Commission originally authorized to be crossed using an open-cut method will enable Mountain Valley to complete construction of this segment. Additionally, Mountain Valley avers no new landowners would be impacted by the change to conventional bore crossings, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

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.

Any questions regarding the proposed project should be directed to Matthew Eggerding, Mountain Valley Pipeline, LLC, 2200 Energy Drive, Canonsburg, Pennsylvania 15317, by phone (412) 553–5786, or by email at *MEggerding@equitransmidstream.com.*

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,[2] within 90 days of this Notice the Commission staff will either: Complete its environmental review 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 final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an 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 FEIS or EA.

Public Participation

There are two ways to become involved in the Commission's review of this project: You can file comments on the project, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on December 21, 2020.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please submit your comments on or before December 21, 2020.

There are three methods you can use to submit your comments to the Commission. In all instances, please reference the Project docket number CP21–12–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the eFiling feature, which is located 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 will be asked to select the type of filing you are making; first select General and then select Comment on a Filing; or

(3) You can file a paper copy of your comments by mailing them to the following address below.[3] Your written comments must reference the Project docket number (CP21–12–000).

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. *However, the filing of a comment alone will not serve to make the filer a party to the proceeding.* To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[4] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure[5] and the regulations under the NGA[6] by the intervention deadline for the project, which is December 21, 2020. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances,

[1] *Mountain Valley Pipeline, LLC,* 161 FERC 61,043 (2017).

[2] 18 CFR (Code of Federal Regulations) 157.9.

[3] Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

[4] 18 CFR 385.102(d).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

please reference the Project docket number CP21–12–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov)* under the link to Documents and Filings. New eFiling users must first create an account by clicking on eRegister. You will be asked to select the type of filing you are making; first select General and then select Intervention. The eFiling feature includes a document-less intervention option; for more information, visit *https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf;* or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below.[7] Your motion to intervene must reference the Project docket number CP21–12–000.

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Motions to intervene must be served on the applicant either by mail or email at: 2200 Energy Drive, Canonsburg, Pennsylvania 15317 or at *MEggerding@equitransmidstream.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed[8] motions to intervene are automatically granted by operation of Rule 214(c)(1).[9] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[10] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link as described above. 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. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on December 21, 2020.

Dated: November 30, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26709 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

[7] Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

[8] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[9] 18 CFR 385.214(c)(1).

[10] 18 CFR 385.214(b)(3) and (d).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4451–024]

Green Mountain Power Corporation, City of Somersworth, New Hampshire; Notice Soliciting Scoping Comments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* 4451–024.

c. *Date Filed:* April 30, 2020.

d. *Submitted By:* Green Mountain Power Corporation and the City of Somersworth, New Hampshire.

e. *Name of Project:* Lower Great Falls Hydroelectric Project.

f. *Location:* On the Salmon Falls River in Strafford County, New Hampshire, and York County, Maine. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. John Greenan, Green Mountain Power Corporation, 1252 Post Road, Rutland, VT 05701; Phone at (802) 770–2195, or email at *john.greenan@greenmountainpower.com.*

i. *FERC Contact:* Amanda Gill at (202) 502–6773; or email at *amanda.gill@ferc.gov.*

j. *Deadline for filing scoping comments:* December 30, 2020.

The Commission strongly encourages electronic filing. Please file scoping comments using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* 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, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Lower Great Falls Hydroelectric Project (P–4451–024).

The Commission's Rules of Practice and Procedure require all interveners 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 intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. The application is not ready for environmental analysis at this time.

l. The existing Lower Great Falls Hydroelectric Project consists of: (1) A 297-foot-long, 32-foot-high stone masonry and concrete dam that includes the following sections: (a) A 176-foot-long spillway section with a crest elevation of 102.37 feet National Geodetic Vertical Datum of 1929 (NGVD 29) with 4-foot-high flashboards at an elevation of 106.37 feet NGVD 29 at the top of the flashboards and a 5.25-foot-wide, 4-foot-high debris sluice gate; (b) a 50-foot-long left abutment section with

two 8-foot-wide, 8-foot-high low-level outlet gates (only one of which is operational), that control flow into two 7-foot-diameter, 40-foot-long outlet pipes; and (c) a 71-foot-long right abutment section; (2) a 40-acre impoundment with a normal surface elevation of 106.37 feet NGVD 29; (3) a 40.5-foot-wide, 20-foot-high intake structure with four 5-foot-wide, 10.5-foot-high steel frame gates and a trashrack with 2-inch bar spacing; (4) an 8.5-foot-diameter, 120-foot-long left, steel penstock that bifurcates into a 5.3-foot-diameter, 85-foot-long section and a 7.6-foot-diameter, 85-foot-long section; (5) an 8.5-foot-diameter, 140-foot-long right, steel penstock that bifurcates into a 7-foot-diameter, 85-foot-long section and a 7.6-foot-diameter, 85-foot-long section; (6) a 46-foot-long, 30-foot-wide concrete and brick powerhouse with two 260-kilowatt (kW) F-type Francis turbine-generator units and two 380-kW F-type Francis turbine-generator units, for a total installed capacity of 1.28 MW; (7) a 55-foot-long, 30-foot-wide tailrace; (8) a 260-foot-long underground transmission line that delivers power to a 4.16-kilovolt distribution line; and (9) appurtenant facilities. The project creates an approximately 250-foot-long bypassed reach of the Salmon Falls River.

The project operates as a run-of-river (ROR) facility with no storage or flood control capacity. The project impoundment is maintained at a flashboard crest elevation of 106.37 feet NGVD. The current license requires the project to maintain a continuous minimum flow of 6.05 cubic feet per second (cfs) or inflow, whichever is less, to the bypassed reach for the purpose of protecting and enhancing aquatic resources in the Salmon Falls River. The average annual generation production of the project was 3,916,825 kilowatt-hours from 2005 through 2018.

The applicant proposes to: (1) Continue operating the project in a ROR mode; (2) provide a minimum flow of 30 cfs or inflow, whichever is less, to the bypassed reach; (3) install an eel ramp for upstream eel passage at the project; (4) implement targeted nighttime turbine shutdowns to protect eels during downstream passage; (5) install a downstream fish passage structure for eels and other fish species.

m. 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 via the internet through the Commission's Home Page (*http://www.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, (866) 208–3676 or TYY, (202) 502–8659.

n. You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. Scoping Process.

Commission staff will prepare either an environmental assessment (EA) or an Environmental Impact Statement (EIS) that describes and evaluates the probable effects, if any, of the licensee's proposed action and alternatives. The EA or EIS will consider environmental impacts and reasonable alternatives to the proposed action. The Commission's scoping process will help determine the required level of analysis and satisfy the NEPA scoping requirements, irrespective of whether the Commission prepares an EA or an EIS. Due to restrictions on mass gatherings related to COVID–19, we do not intend to conduct a public scoping meeting and site visit in this case. Instead, we are soliciting written comments and suggestions on the preliminary list of issues and alternatives to be addressed in the NEPA document, as described in scoping document 1 (SD1), issued November 30, 2020.

Copies of the SD1 outlining the subject areas to be addressed in the NEPA document were distributed to the parties on the Commission's mailing list and the applicant's distribution list. Copies of SD1 may be viewed on the web at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call 1–866–208–3676 or for TTY, (202) 502–8659.

Dated: November 30, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26715 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–2446–002.
Applicants: Bitter Ridge Wind Farm, LLC.
Description: Compliance filing: Revised Rate Schedule FERC No. 1 Under Docket ER20–2446 to be effective 9/15/2020.
Filed Date: 11/30/20.
Accession Number: 20201130–5045
Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–136–000.
Applicants: Flat Ridge 3 Wind Energy, LLC.
Description: Resubmittal of Attachments [Asset Appendix and Exhibit D] to October 16, 2020 Flat Ridge 3 Wind Energy, LLC tariff filing.
Filed Date: 11/25/20.
Accession Number: 20201125–5193.
Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: ER21–497–000.
Applicants: EDF Renewables Development, Inc.
Description: Petition for Limited Waiver, et al. of EDF Renewables Development, Inc.
Filed Date: 11/25/20.
Accession Number: 20201125–5196.
Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: ER21–498–000.
Applicants: Otter Tail Power Company.
Description: § 205(d) Rate Filing: Filing of Revised Certificate of Concurrence—NSP TCEA to be effective 1/4/2021.
Filed Date: 11/30/20.
Accession Number: 20201130–5051.
Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–499–000.
Applicants: New England Power Pool Participants Committee.
Description: § 205(d) Rate Filing: December 2020 Membership Filing to be effective 11/1/2020.
Filed Date: 11/30/20.
Accession Number: 20201130–5093.
Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–500–000.
Applicants: Exelon Generation Company, LLC.
Description: Compliance filing: Reactive Service Rate Schedule Compliance Filing—Request for Expedited Action to be effective 12/17/2020.
Filed Date: 11/30/20.
Accession Number: 20201130–5143.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–501–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Service Agreement Nos. 383 and 384_ Sun Streams to be effective 11/1/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5144.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–502–000.

Applicants: New York Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 205 filing re: 2021–2025 ICAP Demand Curve Reset Proposal to be effective 1/30/2021.

Filed Date: 11/30/20.

Accession Number: 20201130–5146.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–503–000.

Applicants: Alabama Power Company.

Description: Initial rate filing: Cotton Creek Affected System Upgrade Agreement Filing to be effective 10/29/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5175.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–504–000.

Applicants: Georgia Power Company.

Description: Initial rate filing: Cotton Creek Affected System Upgrade Agreement Filing to be effective 10/29/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5176.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–505–000.

Applicants: Mississippi Power Company.

Description: Initial rate filing: Cotton Creek Affected System Upgrade Agreement Filing to be effective 10/29/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5178.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–506–000.

Applicants: Alabama Power Company.

Description: Initial rate filing: Wild Azalea Affected System Upgrade Agreement Filing to be effective 10/29/2020.

Filed Date: 11/30/20..

Accession Number: 20201130–5179.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–507–000.

Applicants: Georgia Power Company.

Description: Initial rate filing: Wild Azalea Affected System Upgrade Agreement Filing to be effective 10/29/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5182.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–508–000.

Applicants: Mississippi Power Company.

Description: Initial rate filing: Wild Azalea Affected System Upgrade Agreement Filing to be effective 10/29/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5183.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–509–000.

Applicants: Alabama Power Company.

Description: Initial rate filing: Flowers Creek Affected System Upgrade Agreement Filing to be effective 10/29/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5185.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–510–000.

Applicants: Georgia Power Company.

Description: Initial rate filing: Flowers Creek Affected System Upgrade Agreement Filing to be effective 10/29/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5187.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–511–000.

Applicants: Safe Harbor Water Power Corporation.

Description: § 205(d) Rate Filing: Revised Reactive Service Tariff and Requests for Waiver and Expedited Action to be effective 1/1/2021.

Filed Date: 11/30/20.

Accession Number: 20201130–5190.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–512–000.

Applicants: Mississippi Power Company.

Description: Initial rate filing: Flowers Creek Affected System Upgrade Agreement Filing to be effective 10/29/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5195.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–513–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: November 2020 Western WDT Service Agreement Biannual Filing to be effective 2/1/2021.

Filed Date: 11/30/20.

Accession Number: 20201130–5198.

Comments Due: 5 p.m. ET 12/21/20.

Docket Numbers: ER21–514–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: November 2020 Western Interconnection Agreement Biannual Filing to be effective 2/1/2021.

Filed Date: 11/30/20.

Accession Number: 20201130–5201.

Comments Due: 5 p.m. ET 12/21/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by 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: November 30, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26716 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–13–000]

Southern Natural Gas Company LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on November 20, 2020, Southern Natural Gas Company, LLC, 569 Brookwood Village, Suite 749, Birmingham, Alabama 35209, filed in the above referenced docket a prior notice pursuant to Section 157.210 and 157.216 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act, seeking authorization to replace approximately 0.81 miles of 14-inch pipe on its Chattanooga Branch Line with 20-inch pipe, abandon in place approximately 0.81 miles of the 14″ Chattanooga Branch Line being replaced with the larger diameter pipeline, and perform minor modifications at its Dalton #2 Meter Station in order to accommodate increased deliveries of natural gas to Dalton Utilities located in Whitfield County, Georgia. Southern proposes to abandon these facilities under authorities granted by its blanket certificate issued in Docket No. CP82–

406–000.[1] Southern estimates the cost of the project to be $4,067,101, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

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.

Any questions concerning this application should be directed to Tina S. Hardy, Manager Regulatory, (205)325–3668, *tina_hardy@kindermorgan.com,* P.O. Box 2563, Birmingham, Alabama 35202–2563.

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on January 29, 2021. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is January 29, 2021. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is January 29, 2021. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before January 29, 2021. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP21–13–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov)* under the link to Documents and Filings. New eFiling users must first create an account by clicking on eRegister. You will be asked to select the type of filing you are making; first select General and then select Protest, Intervention, or Comment on a Filing; or [7]

(2) You can file a paper copy of your submission by mailing it to the address below.[8] Your submission must reference the Project docket number CP21–13–000.

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: *tina_hardy@kindermorgan.com,* P. O. Box 2563, Birmingham, Alabama 35202–2563. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

[1] *Southern Natural Gas Company,* 20 FERC ¶ 62,414 (1982).

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

[7] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

[8] Hand-delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Tracking the proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link as described above. 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. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: November 30, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26710 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Number: PR21–7–000.

Applicants: Louisville Gas and Electric Company.

Description: Tariff filing per 284.123(b), (e)/:Revised Statement of Operating Conditions to be effective 11/1/2020.

Filed Date: 11/27/20.

Accession Number: 20201127–5000.

Comments/Protests Due: 5 p.m. ET 12/18/2020.

Docket Numbers: RP21–258–000.

Applicants: Adelphia Gateway, LLC.

Description: § 4(d) Rate Filing: Adelphia Tariff Update filing 11–30–20 to be effective 12/30/2020.

Filed Date: 11/30/20.

Accession Number: 20201130–5030

Comments Due: 5 p.m. ET 12/14/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by 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: November 30, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26707 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Number: PR21–6–000.

Applicants: ONEOK WesTex Transmission, L.L.C.

Description: Submits tariff filing per 284.123(b), (e)+(g): 2020 Revised Statement of Operating Conditions to be effective 12/1/2020 under PR21–6.

Filed Date: 11/25/2020.

Accession Number: 202011255047.

Comments Due: 5 p.m. ET 12/16/2020.

284.123(g) Protests Due: 5 p.m. ET 1/25/2021.

Docket Numbers: RP21–255–000.

Applicants: TransColorado Gas Transmission Company LLC.

Description: § 4(d) Rate Filing: Quarterly Fuel and Lost and Unaccounted For Percentage Update to be effective 1/1/2021.

Filed Date: 11/25/20.

Accession Number: 20201125–5008.

Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–256–000.

Applicants: Mojave Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Annual Fuel and L&U Filing 2021 to be effective 1/1/2021.

Filed Date: 11/25/20.

Accession Number: 20201125–5020.

Comments Due: 5 p.m. ET 12/7/20.

Docket Numbers: RP21–257–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (Conoco Dec 20) to be effective 12/1/2020.

Filed Date: 11/25/20.

Accession Number: 20201125–5023.

Comments Due: 5 p.m. ET 12/7/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–26714 Filed 12–3–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9054–2]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed November 20, 2020 10 a.m. EST Through November 30, 2020 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20200243, Final, BR, ND, Eastern North Dakota Alternate Water Supply Project, Review Period Ends: 01/04/2021, Contact: Damien Reinhart 701–221–1275.

EIS No. 20200244, Final, USAF, FL, F–35A Wing Beddown at Tyndall AFB and MQ–9 Wing Beddown at Tyndall AFB or Vandenberg AFB, Review

Period Ends: 01/04/2021, Contact: Nolan Swick 210–925–3392.

EIS No. 20200245, Draft, BLM, NV, Robinson Mine Plan of Operations Amendment, Comment Period Ends: 01/19/2021, Contact: Tiera Arbogast 775–293–5042.

EIS No. 20200246, Final, BLM, AK, Bering Sea-Western Interior Proposed Resource Management Plan and Final Environmental Impact Statement, Review Period Ends: 01/04/2021, Contact: Jorjena Barringer 907–267–1246.

EIS No. 20200247, Final, USFWS, BLM, NV, Thacker Pass Lithium Mine Project, Review Period Ends: 01/04/2021, Contact: Ken Loda 775–623–1500.

EIS No. 20200248, Final, USFS, AZ, Fossil Creek Wild and Scenic River Comprehensive River Management Plan, Review Period Ends: 01/19/2021, Contact: Mike Dechter 928–527–3416.

Dated: November 30, 2020.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2020–26692 Filed 12–3–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of December 1, 2020, Federal Accounting Standards Advisory Board Meeting

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and the FASAB Rules Of Procedure, as amended in October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) will hold a meeting on December 1, 2020. The purpose of the meeting is to discuss issues related to the accounting and reporting of government land.

The meeting will begin at 2 p.m. and conclude before 5 p.m. The meeting will be virtual, and observers can listen to the meeting via a teleconference line. The teleconference line is 1–877–446–3914. Please enter the following listen only passcode 7381305#. For any questions concerning the meeting or during the meeting please send an email to *fasab@fasab.gov*. The agenda and briefing materials will be available at *https://www.fasab.gov/briefing-materials/approximately* one week before the meeting.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act (5 U.S.C. App.).

Dated: November 10, 2020.

Monica R. Valentine,

Executive Director.

[FR Doc. 2020–26725 Filed 12–3–20; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Request for Comment on a Proposed Joint Exposure Draft, Implementation Guidance for Leases and Omnibus Amendments to Leases-Related Topics

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and the FASAB Rules Of Procedure, as amended in October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued a joint exposure draft of a proposed Federal Financial Accounting Technical Release (TR) titled *Implementation Guidance for Leases* and a proposed Statement of Federal Financial Accounting Standards (SFFAS) titled *Omnibus Amendments to Leases-Related Topics.*

The exposure draft is available on the FASAB website at *https://www.fasab.gov/documents-for-comment/.* Copies can be obtained by contacting FASAB at (202) 512–7350.

Respondents are encouraged to comment on any part of the joint exposure draft. Written comments are requested by February 5, 2021, and should be sent to *fasab@fasab.gov* or Monica R. Valentine, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street NW, Suite 1155, Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act (5 U.S.C. App.), 31 U.S.C. 3511(d).

Dated: November 10, 2020.

Monica R. Valentine,

Executive Director.

[FR Doc. 2020–26724 Filed 12–3–20; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Request for Comment on the Exposure Draft of a Proposed Interpretation of Federal Financial Accounting Standards, Clarification of Non-Federal Non-Entity FBWT Classification (SFFAS 1, Paragraph 31): An Interpretation of SFFAS 1 and SFFAS 31

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and the FASAB Rules Of Procedure, as amended in October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued an exposure draft of a proposed Interpretation of Federal Financial Accounting Standards titled *Clarification of Non-Federal Non-Entity FBWT Classification (SFFAS 1, Paragraph 31): An Interpretation of SFFAS 1 and SFFAS 31.*

The exposure draft is available on the FASAB website at *https://www.fasab.gov/documents-for-comment/.* Copies can be obtained by contacting FASAB at (202) 512–7350.

Respondents are encouraged to comment on any part of the exposure draft. Written comments are requested by January 6, 2021, and should be sent to *fasab@fasab.gov* or Monica R. Valentine, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street NW, Suite 1155, Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act (5 U.S.C. App.), 31 U.S.C. 3511(d).

Dated: November 10, 2020.

Monica R. Valentine,

Executive Director.

[FR Doc. 2020–26723 Filed 12–3–20; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL COMMUNICATIONS COMMISSION

[WC Docket Nos. 10–90, 07–135, 05–337, 03–109; CC Docket Nos. 01–92, 96–45; GN Docket No. 09–51; WT Docket No. 10–208; DA 20–1279; FR ID 17232]

Wireline Competition Bureau Dismisses Seven Petitions for Reconsideration of Aspects of the USF/ICC Transformation Order

AGENCY: Federal Communications Commission.

ACTION: Notice of dismissal of petitions for reconsideration.

SUMMARY: The Wireline Competition Bureau (Bureau) received no objections to dismissing seven petitions for reconsideration and/or clarification of various aspects of the *USF/ICC Transformation Order,* and dismisses those petitions with prejudice. One party filed an objection to dismissing the petition for reconsideration by the Public Service Commission of the District of Columbia (DC PSC), and the Bureau declines to dismiss that petition at this time.

DATES: This action is effective as of January 4, 2021.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Marvin Sacks, Wireline Competition Bureau, Pricing Policy Division via phone at (202) 418–1540 or email at *marvin.sacks@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Public Notice,* DA 20–1279, released on October 30, 2020. A full-text version of this document can be found at the following internet address: *https://docs.fcc.gov/public/attachments/DA-20-1279A1.pdf.*

To efficiently resolve issues that are no longer contested, the Bureau announces through this document the dismissal of seven petitions for reconsideration and/or clarification of various aspects of the *Universal Service Fund/Intercarrier Compensation (USF/ICC) Transformation Order.* 26 FCC Rcd 17663; 76 FR 73830, November 29, 2011.

On January 14, 2020, the Bureau released a *Public Notice* providing petitioners notice of and an opportunity to object to the Bureau's plan to dismiss with prejudice eight pending petitions for reconsideration and/or clarification of various aspects of the *USF/ICC Transformation Order.* 35 FCC Rcd 492; 85 FR 12747, March 4, 2020. No entities had filed comments or *ex parte* submissions regarding any of the eight petitions for several years.

The Bureau received no objections to the dismissal of the seven petitions identified in the chart below, and we therefore dismiss those petitions with prejudice.

Petitioner	Petition	Date petition filed
MetroPCS Communications, Inc	Petition of MetroPCS Communications, Inc. for Clarification and Limited Reconsideration of aspects of the *USF/ICC Transformation Order.*	12/29/2011
National Exchange Carrier Association, Inc.; Organization for the Promotion and Advancement of Small Telecommunications Companies; and Western Telecommunications Alliance (Rural Associations).	Petition for Reconsideration and Clarification of aspects of the *USF/ICC Transformation Order.*	12/29/2011
NTCH, Inc	Petition for Reconsideration of aspects of the *USF/ICC Transformation Order.*	12/29/2011
Onvoy, Inc. and its affiliate, 360networks (USA) Inc	Petition for Clarification or Reconsideration of an aspect of the *USF/ICC Transformation Order.*	12/23/2011
Sprint Nextel Corporation	Petition for Reconsideration and Clarification of aspects of the *USF/ICC Transformation Order.*	12/29/2011
United States Telecom Association	Petition for Reconsideration and Clarification of aspects of the *USF/ICC Transformation Order.*	12/29/2011
Verizon (Verizon Communications Inc. and Verizon Wireless) (Verizon Petition).	Petition for Clarification or, in the Alternative, for Reconsideration of aspects of the *USF/ICC Transformation Order.*	12/29/2011

In light of an objection that we received from the Pennsylvania Public Utility Commission to the dismissal of a petition for reconsideration of an aspect of the *USF/ICC Transformation Order* by the DC PSC filed on December 28, 2011, we decline to dismiss that petition at this time.

Federal Communications Commission.

Daniel Kahn,

Associate Bureau Chief, Wireline Competition Bureau.

[FR Doc. 2020–26748 Filed 12–3–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1004; FRS 17277]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

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) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. 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 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 Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before February 2, 2021. 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 contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1004.

Title: Commission's Rules to Ensure Compatibility with Enhanced 911 Emergency Calling Systems.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 235 respondents; 565 responses.

Estimated Time per Response: 3.8 hours.

Frequency of Response: One-time and quarterly reporting requirements.

Obligation to Respond: Mandatory. Statutory authority for this collection of information is contained in 47 U.S.C. 1, 4(i), 201, 303, 309 and 332 of the Communications Act of 1934, as amended.

Total Annual Burden: 2,145 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The existing information collection is based on the Commission's regulatory authority pursuant to its regulatory responsibilities under the Omnibus Budget Reconciliation Act of 1993 (''OBRA–1993''), which added Section 309(j) to the Communications Act of 1934. Given that delays in compliance could impact the delivery of safety-of-life services to the public, it is imperative that the CMRS carriers be brought into compliance, required in the various orders, and that the reports and compliance plans be timely submitted by the carriers.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–26745 Filed 12–3–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1030; FRS 17271]

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 of 1995 (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 PRA comments should be submitted on or before February 2, 2021. 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 contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *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:

OMB Control Number: 3060–1030.

Title: Service Rules for Advanced Wireless Services (AWS) in the 1.7 GHz and 2.1 GHz Bands.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; state, local, or tribal government; Federal Government and not for profit institutions.

Number of Respondents: 232 respondents; 6,812 responses.

Estimated Time per Response: 0.25 to 5 hours.

Frequency of Response: Annual, semi-annual, one time, and on occasion reporting requirements, recordkeeping requirement, third-party disclosure requirements, and every ten years reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in sections 1, 2, 4(i), 201, 301, 302, 303, 307, 308, 309, 310, 316, 319, 324, 332, and 333 of the Communications Act of 1934, as amended, and sections 6003, 6004, and 6401 of the Middle Class Tax Relief Act of 2012, Public Law 112–96, 126 Stat. 156, 47 U.S.C. 151, 152, 154(i), 201, 301, 302(a), 303, 307, 308, 309, 310, 316, 319, 324, 332, 333, 1403, 1404, and 1451.

Total Annual Burden: 13,866 hours.

Total Annual Cost: $782,618.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The currently approved information collections under Control No. 3060–1030 relate to three groups of Advanced Wireless Service (''AWS'') spectrum, commonly referred to as AWS–1, AWS–3, and AWS–4. The FCC's policies and rules apply to application, licensing, operating and technical rules for this spectrum. The respondents are AWS licensees, incumbent Fixed Microwave Service (FS) and Broadband Radio Service (BRS) licensees that relocate out of the AWS bands, and AWS Clearinghouses that keep track of cost sharing obligations. AWS licensees also have coordination requirements with certain Federal Government incumbents.

Recordkeeping, reporting, and third-party disclosure requirements associated with the FCC items listed in item 1 will be used by incumbent

licensees and new entrants to negotiate relocation agreements and to coordinate operations to avoid interference. The information also will be used by the clearinghouses to maintain a national database, determine reimbursement obligations of entrants pursuant to the Commission's rules, and notify such entrants of their reimbursement obligations. Additionally, the information will be used to facilitate dispute resolution and for FCC oversight of the clearinghouses and the cost-sharing plan.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–26743 Filed 12–3–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0057, FRS 17278]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission 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 and recommendations for the proposed information collection should be submitted on or before January 4, 2021.

ADDRESSES: Comments should be sent 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. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) 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; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) 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. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–0057.

Title: Application for Equipment Authorization, FCC Form 731.

Form Number: FCC 731.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 11,305 respondents; 24,873 responses.

Estimated Time per Response: 8.11 hours (rounded up).

Frequency of Response: On occasion reporting requirement; one-time reporting requirement and third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in the 47 U.S.C. 154(i), 301, 302, 303(e), 303(f) and 303(r).

Total Annual Burden: 201,603 hours.

Total Annual Costs: $ 50,155,140.

Privacy Act Impact Assessment: Yes. The personally identifiable information (PII) in this information collection is covered by a Privacy Impact Assessment (PIA), Equipment Authorizations Records and Files Information System. It is posted at: *https://www.fcc.gov/general/privacy-act-information#pia.*

Nature and Extent of Confidentiality: Minimal exemption from the Freedom of Information Act (FOIA) under 5 U.S.C. 552(b)(4) and FCC rules under 47 CFR 0.457(d) is granted for trade secrets which may be submitted as attachments to the application FCC Form 731. No other assurances of confidentiality are provided to respondents.

Needs and Uses: The Commission will submit this revised information collection to the Office of Management and Budget (OMB) after this 60-day comment period to obtain the three-year clearance.

The December 2019 radiofrequency (RF) exposure Second Report and Order, ET Docket Nos. 03–137 and 13–184, FCC 19–126, included amendments to rule sections 1.1307, 2.1091, and 2.1093 requiring approval by OMB under the Paperwork Reduction Act. Revision to information collection effected by amendments to rule sections 2.1091 and 2.1093 is reported herein. Revision to information collection effected by amendments to rule section 1.1307 is reported separately under OMB 3060–0004.

In amendments to rule sections 2.1091 and 2.1093, the Commission revised its implementing rules to reflect modern technology and today's uses. We replaced a requirement which relied on consideration of the rule part under which the equipment would operate, the portion of the electromagnetic spectrum where the equipment is

designed to operate, and technical characteristics of the equipment to determine if the equipment would be subject to routine environmental evaluation for RF exposure prior to equipment authorization. The rule modifications adopted a formula for evaluation of compliance with RF exposure limits and determination whether an environmental assessment would need to be prepared if the limits are exceeded. The amended rules provide more efficient, practical, and consistent RF exposure evaluation procedures and mitigation measures to help ensure compliance with the existing RF exposure limits.

RF equipment manufacturers must comply with the requirements of rule sections 2.1091 and 2.1093 when submitting an application for certification under rule section 2.1033. The changes to rule sections 2.1091 and 2.1093 will not affect the number of respondents or number of responses associated with this information collection. Although the new rules will modify the way applicants evaluate RF compliance when they apply for equipment authorization, we believe that it will take, on average, the same time that it takes for applicants to make this evaluation under our existing rules.

The latest RF exposure Second Report and Order, ET Docket Nos. 03–137 and 13–184, FCC 19–126, amended rule sections 2.1091 by revising paragraphs (b), (c), (d)(1), and (d)(2) and 2.1093 by revising paragraphs (b), (c) and (d) to read as follows:

§ 2.1091 Radiofrequency radiation exposure evaluation: Mobile devices.

* * * * *

(b) For purposes of this Section, the definitions in Section 1.1307(b)(2) of this chapter shall apply. A mobile device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that a separation distance of at least 20 centimeters is normally maintained between the RF source's radiating structure(s) and the body of the user or nearby persons. In this context, the term ''fixed location'' means that the device is physically secured at one location and is not able to be easily moved to another location while transmitting. Transmitting devices designed to be used by consumers or workers that can be easily re-located, such as wireless devices associated with a personal desktop computer, are considered to be mobile devices if they meet the 20-centimeter separation requirement.

(c)(1) Evaluation of compliance with the exposure limits in Section 1.1310 of this chapter, and preparation of an EA if the limits are exceeded, is necessary for mobile devices with single RF sources having either more than an available maximum time-averaged power of 1 mW or more than the ERP listed in Table 1 of Section 1.1307(b)(3)(i)(C), whichever is greater. For mobile devices not exempt by Section 1.1307(b)(3)(i)(C) at distances from 20 centimeters to 40 centimeters and frequencies from 0.3 GHz to 6 GHz, evaluation of compliance with the exposure limits in Section 1.1310 of this chapter is necessary if the ERP of the device is greater than $ERP_{20\ cm}$ in the formula below. If the ERP of a single RF source at distances from 20 centimeters to 40 centimeters and frequencies from 0.3 GHz to 6 GHz is not easily obtained, then the available maximum time-averaged power may be used (*i.e.,* without consideration of ERP) in comparison with the following formula only if the physical dimensions of the radiating structure(s) do not exceed the electrical length of λ/4 or if the antenna gain is less than that of a half-wave dipole (1.64 linear value).

$$P_{th}(\text{mW}) = ERP_{20\ cm}\ (\text{mW}) = \begin{cases} 2040f & 0.3\ \text{GHz} \leq f < 1.5\ \text{GHz} \\ 3060 & 1.5\ \text{GHz} \leq f \leq 6\ \text{GHz} \end{cases}$$

(2) For multiple mobile or portable RF sources within a device operating in the same time averaging period, routine environmental evaluation is required if the formula in Section 1.1307(b)(3)(ii)(B) of this chapter is applied to determine the exemption ratio and the result is greater than 1.

(3) Unless otherwise specified in this chapter, any other single mobile or multiple mobile and portable RF source(s) associated with a device is exempt from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in Sections 1.1307(c) and 1.1307(d) of this chapter.

(d)(1) Applications for equipment authorization of mobile RF sources subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in Section 1.1310 of this chapter as part of their application. Technical information showing the basis for this statement must be submitted to the Commission upon request. In general, maximum time-averaged power levels must be used for evaluation. All unlicensed personal communications service (PCS) devices and unlicensed NII devices shall be subject to the limits for general population/uncontrolled exposure.

(2)(i) For purposes of analyzing mobile transmitting devices under the occupational/controlled criteria specified in Section 1.1310 of this chapter, time averaging provisions of the limits may be used in conjunction with the maximum duty factor to determine maximum time-averaged exposure levels under normal operating conditions.

(2)(ii) Such time averaging provisions based on maximum duty factor may not be used in determining exposure levels for devices intended for use by consumers in general population/uncontrolled environments as defined in Section 1.1310 of this chapter. However, ''source-based'' time averaging based on an inherent property of the RF source is allowed over a time period not to exceed 30 minutes. An example of this is the determination of exposure from a device that uses digital technology such as a time-division multiple-access (TDMA) scheme for transmission of a signal.

* * * * *

Section 2.1093 is amended by revising paragraphs (b), (c), and (d) to read as follows:

§ 2.1093 Radiofrequency radiation exposure evaluation: Portable devices.

* * * * *

(b) For purposes of this section, the definitions in Section 1.1307(b)(2) of this chapter shall apply. A portable device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that the RF source's radiating structure(s) is/are within 20 centimeters of the body of the user.

(c)(1) Evaluation of compliance with the exposure limits in Section 1.1310 of this chapter, and preparation of an EA if the limits are exceeded, is necessary for portable devices having single RF sources with more than an available maximum time-averaged power of 1

mW, more than the ERP listed in Table 1 of Section 1.1307(b)(3)(i)(C), or more than the P_{th} in the following formula, whichever is greater. The following formula shall only be used in conjunction with portable devices not exempt by Section 1.1307(b)(3)(i)(C) at distances from 0.5 centimeters to 20 centimeters and frequencies from 0.3 GHz to 6 GHz.

$$P_{th}\ (\text{mW}) = \begin{cases} ERP_{20\ cm}(d/20\ \text{cm})^{x} & d \leq 20\ \text{cm} \\ ERP_{20\ cm} & 20\ \text{cm} < d \leq 40\ \text{cm} \end{cases}$$

Where

$$x = -\log_{10}\left(\frac{60}{ERP_{20\ cm}\sqrt{f}}\right) \text{ and f is in GHz;}$$

$$ERP_{20\ cm}\ (\text{mW}) = \begin{cases} 2040f & 0.3\ \text{GHz} \leq f < 1.5\ \text{GHz} \\ 3060 & 1.5\ \text{GHz} \leq f \leq 6\ \text{GHz} \end{cases}$$

d = the minimum separation distance (cm) in any direction from any part of the device antenna(s) or radiating structure(s) to the body of the device user.

(2) For multiple mobile or portable RF sources within a device operating in the same time averaging period, evaluation is required if the formula in Section 1.1307(b)(3)(ii)(B) of this chapter is applied to determine the exemption ratio and the result is greater than 1.

(3) Unless otherwise specified in this chapter, any other single portable or multiple mobile and portable RF source(s) associated with a device is exempt from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in Sections 1.1307(c) and 1.1307(d) of this chapter.

(d)(1) Applications for equipment authorization of portable RF sources subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in Section 1.1310 of this chapter as part of their application. Technical information showing the basis for this statement must be submitted to the Commission upon request. The SAR limits specified in Sections 1.1310(a) through (c) of this chapter shall be used for evaluation of portable devices transmitting in the frequency range from 100 kHz to 6 GHz. Portable devices that transmit at frequencies above 6 GHz shall be evaluated in terms of the MPE limits specified in Table 1 of Section 1.1310(e)(1) of this chapter. A minimum separation distance applicable to the operating configurations and exposure conditions of the device shall be used for the evaluation. In general, maximum time-averaged power levels must be used for evaluation. All unlicensed personal communications service (PCS) devices and unlicensed NII devices shall be subject to the limits for general population/uncontrolled exposure.

(2) Evaluation of compliance with the SAR limits can be demonstrated by either laboratory measurement techniques or by computational modeling. The latter must be supported by adequate documentation showing that the numerical method as implemented in the computational software has been fully validated; in addition, the equipment under test and exposure conditions must be modeled according to protocols established by FCC-accepted numerical computation standards or available FCC procedures for the specific computational method. Guidance regarding SAR measurement techniques can be found in the Office of Engineering and Technology (OET) Laboratory Division Knowledge Database (KDB). The staff guidance provided in the KDB does not necessarily represent the only acceptable methods for measuring RF exposure or RF emissions, and is not binding on the Commission or any interested party.

(3) For purposes of analyzing portable RF sources under the occupational/controlled SAR criteria specified in Section 1.1310 of this chapter, time averaging provisions of the limits may be used in conjunction with the maximum duty factor to determine maximum time-averaged exposure levels under normal operating conditions.

(4) The time averaging provisions for occupational/controlled SAR criteria, based on maximum duty factor, may not be used in determining typical exposure levels for portable devices intended for use by consumers, such as cellular telephones, that are considered to operate in general population/uncontrolled environments as defined in Section 1.1310 of this chapter. However, ''source-based'' time averaging based on an inherent property of the RF source is allowed over a time period not to exceed 30 minutes. An example of this would be the determination of exposure from a device that uses digital technology such as a time-division multiple-access (TDMA) scheme for transmission of a signal.

(5) Visual advisories (such as labeling, embossing, or on an equivalent electronic display) on portable devices designed only for occupational use can be used as part of an applicant's evidence of the device user's awareness of occupational/controlled exposure limits. Such visual advisories shall be legible and clearly visible to the user from the exterior of the device. Visual advisories must indicate that the device is for occupational use only, refer the user to specific information on RF exposure, such as that provided in a user manual and note that the advisory and its information is required for FCC RF exposure compliance. Such instructional material must provide users with information on how to use the device and to ensure users are *fully aware* of and able to *exercise control* over their exposure to satisfy compliance with the occupational/controlled exposure limits. A sample of the visual advisory, illustrating its location on the device, and any instructional material intended to accompany the device when marketed, shall be filed with the Commission along with the application for equipment authorization. Details of any special training requirements pertinent

to mitigating and limiting RF exposure should also be submitted. Holders of grants for portable devices to be used in occupational settings are encouraged, but not required, to coordinate with end-user organizations to ensure appropriate RF safety training.

(6) General population/uncontrolled exposure limits defined in Section 1.1310 of this chapter apply to portable devices intended for use by consumers or persons who are exposed as a consequence of their employment and may not be fully aware of the potential for exposure or cannot exercise control over their exposure. No communication with the consumer including either visual advisories or manual instructions will be considered sufficient to allow consumer portable devices to be evaluated subject to limits for occupational/controlled exposure specified in Section 1.1310 of this chapter.

* * * * *

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–26750 Filed 12–3–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1250, FRS 17273]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission 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 and recommendations for the proposed information collection should be submitted on or before January 4, 2021.

ADDRESSES: Comments should be sent 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. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) 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; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) 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. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–1250.

Title: Sections 15.37(k), 74.851(k), and 74.851(l), Consumer Disclosure and Labeling.

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households, Business or other for-profit, and Not-for-profit institutions.

Number of Respondents and Responses: 100 respondents; 2,250 responses.

Estimated Time per Response: 0.25 hours.

Frequency of Response: Third party disclosure requirement (disclosure and labeling requirement).

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in 47 U.S.C. 151, 154(i), 154(j), 301, 302a, 303(f), 303(g), and 303(r).

Total Annual Burden: 625 hours.

Total Annual Cost: $62,500.

Privacy Act Impact Assessment: While this collection of information collection may impact individuals and households, it does not involve the collection of personally identifiable information and therefore does not implicate the Privacy Act.

Nature and Extent of Confidentiality: No information is requested that would require assurance of confidentiality.

Needs and Uses: The Commission will submit this information collection as a revision to the Office of Management and Budget (OMB) after this 60-day comment period to obtain the full three-year clearance from them.

The labeling requirement is applicable to persons who manufacture, sell, lease, or offer for sale or lease, wireless microphone or video assist devices *to the extent that these devices are capable of operating on the specific frequencies associated with the 600 MHz service band (617–652 MHz/663–698 MHz).* This revision recognizes that a requirement for consumer disclosure at the point of sale or lease that was previously part of this information collection no longer affects any party since wireless microphone users must have ceased any wireless microphone operations in the 600 MHz service band no later than July 13, 2020.

Federal Communications Commission.

Marlene Dortch,

Secretary,Office of the Secretary.

[FR Doc. 2020–26742 Filed 12–3–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0182; FRS 17272]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

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 of 1995 (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 PRA comments should be submitted on or before February 2, 2021. 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 contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *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:

OMB Control Number: 3060–0182.

Title: Section 73.1620, Program Tests.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Businesses or other for-profit, Not-for-profit institutions.

Number of Respondents and Responses: 1,470 respondents; 1,470 responses.

Estimated Time per Response: 1–5 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 154(i) of the Communications Act of 1934, as amended.

Total Annual Burden: 1,521 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection.

Needs and Uses: The information collection requirements for this collection are as follows:

47 CFR 73.1620(a)(1) require permittees of a nondirectional AM or FM station, or a nondirectional or directional TV station to notify the FCC upon beginning of program tests. An application for license must be filed within 10 days of this notification.

47 CFR 73.1620(a)(2) require a permittee of an AM or FM station with a directional antenna to file a request for program test authority 10 days prior to date on which it desires to begin program tests. This is filed in conjunction with an application for license.

47 CFR 73.1620(a)(3) require a licensee of an FM station replacing a directional antenna without changes to file a modification of the license application within 10 days after commencing operations with the replacement antenna.

47 CFR 73.1620(a)(4) requires a permittee of an AM station with a directional antenna to file a request for program test authority 10 days prior to the date on which it desires to begin program test.

47 CFR 73.1620(a)(5) requires that, except for permits subject to successive license terms, a permittee of an LPFM station may begin program tests upon notification to the FCC in Washington, *8992 DC provided that within 10 days thereafter an application for license is filed. Program tests may be conducted by a licensee subject to mandatory license terms only during the term specified on such license authorization.

47 CFR 73.1620(b) allows the FCC to right to revoke, suspend, or modify program tests by any station without right of hearing for failure to comply adequately with all terms of the construction permit or the provision of 47 CFR 73.1690(c) for a modification of license application, or in order to resolve instances of interference. The FCC may also require the filing of a construction permit application to bring the station into compliance with the Commission's rules and policies.

47 CFR 73.1620(f) requires licensees of UHF TV stations, assigned to the same allocated channel which a 1,000 watt UHF translator station is authorized to use, to notify the licensee of the translator station at least 10 days prior to commencing or resuming operation and certify to the FCC that such advance notice has been given.

47 CFR 73.1620(g) requires permittees to report any deviations from their promises, if any, in their application for license to cover their construction permit (FCC Form 302) and on the first anniversary of their commencement of program tests.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–26746 Filed 12–3–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1158; FRS 17279]

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 of 1995 (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 PRA comments should be submitted on or before February 2, 2021. 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 contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1158.

Title: Transparency Rule Disclosures, Restoring internet Freedom, Report and Order, WC Docket No. 17–108.

Form Number: N/A.

Type of Review: Extension of a currently-approved collection.

Respondents: Business or other for-profit entities, Not-for-profit entities; State, local, or Tribal governments.

Number of Respondents and Responses: 2,165 respondents; 2,165 responses.

Estimated Time per Response: 26 hours.

Frequency of Response: On occasion reporting requirement; third party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for these collections is contained in Section 257 of the Communications Act of 1934, as amended, 47 U.S.C. Section 257.

Total Annual Burden: 56,290 hours.

Total Annual Cost: $510,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this information collection.

Needs and Uses: The Restoring internet Freedom Report and Order (Restoring internet Freedom Order) revised the information collection requirements applicable to internet service providers (ISPs). The Open internet Order, adopted in 2010, required ISPs to disclose certain network management processes, performance characteristics, and other attributes of broadband internet access service. These disclosure requirements were significantly increased by the Title II Order, adopted in 2015. The Restoring internet Freedom Order eliminated the additional collection imposed by the Title II Order, and added a few discrete elements to the Open internet Order's information collection requirements. The Restoring internet Freedom Order requires an ISP to publicly disclose network management practices, performance, and commercial terms of its broadband internet access service sufficient to enable consumers to make informed choices regarding the purchase and use of such services, and entrepreneurs and other small businesses to develop, market, and maintain internet offerings. As part of these disclosures, the rule requires ISPs to disclose their congestion management, application-specific behavior, device attachment rules, and security practices, as well as any blocking, throttling, affiliated prioritization, or paid prioritization in which they engage. The rule also requires ISPs to disclose performance characteristics, including a service description and the impact of nonbroadband internet access services data services. Finally, the rule requires ISPs to disclose the price of the service, privacy policies, and redress options. The rule requires ISPs to make such disclosures available either via a publicly-available, easily accessible website or through transmittal to the Commission, which will make such disclosures available via a publicly-available, easily accessible website. The information collection will assist the Commission in its statutory obligation to report to Congress on market entry barriers in the telecommunications market. The Commission anticipates that the revised disclosures would empower consumers and businesses with information about their broadband internet access service, protecting the openness of the internet. Although this collection was bifurcated in 2016 with respect to fixed and mobile ISPs, the Commission seeks to have this collection encompass both fixed and mobile ISPs.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–26744 Filed 12–3–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201333–001.

Agreement Name: North Carolina-Virginia Port Terminal Cooperative Working Agreement.

Parties: North Carolina State Ports Authority; Virginia International Terminals, LLC; and the Virginia Port Authority.

Filing Party: David Monroe; GKG Law, P.C.

Synopsis: The amendment extends the Agreement through December 31, 2021. The parties request expedited review.

Proposed Effective Date: 1/7/2021.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/27474.

Dated: December 1, 2020.

Rachel Dickon,

Secretary.

[FR Doc. 2020–26719 Filed 12–3–20; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

TIME AND DATE: December 9, 2020; 10:00 a.m.

PLACE: This meeting will be held by video-conference only.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

1. Briefing by Commissioner Dye on Fact Finding No. 29.
2. Staff Update on General Prohibitions in the Shipping Act.

3. Briefing by Inspector General Jon Hatfield.

CONTACT PERSON FOR MORE INFORMATION: Rachel Dickon, Secretary, (202) 523–5725.

Rachel Dickon,

Secretary.

[FR Doc. 2020–26851 Filed 12–2–20; 4:15 pm]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than December 21, 2020.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *MoCorp, Inc. Iron River, Michigan;* to retain voting shares of MSB Bankshares, Inc., and thereby indirectly retain voting shares of The Miners State Bank, also of Iron River, Michigan.

Board of Governors of the Federal Reserve System, December 1, 2020.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2020–26739 Filed 12–3–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–18F5]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by February 2, 2021.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations, Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–18F5 Application for Enrollment in Medicare Part A internet Claim (iClaim) Application Screen Modernized Claims System and Consolidated Claim Experience Screens.

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Application for Enrollment in Medicare Part A internet Claim (iClaim) Application Screen Modernized Claims System and Consolidated Claim Experience Screens; *Use:* Individuals who are already entitled to retirement or disability benefits under Social Security or Railroad Retirement Board (RRB) benefits are automatically entitled to premium-free Medicare Hospital Insurance (Part A) when they attain age

65 or reach the 25th month of disability benefit entitlement. These individuals do not file a separate application for Medicare Part A because their application for Social Security or RRB benefits is also an application for Part A. The form is for individuals who are not eligible for Social Security for RRB benefits, but may qualify for premium-free Medicare Part A based on certain requirements outlined in § 406.11 and 406.15 or for certain disabled individuals who may enroll in premium Medicare Part A based on certain requirements outlined in § 406.20. Individuals may also choose to enroll in Medicare Part B at the same time they apply for Medicare Part A.

The Application for Enrollment in Medicare Part A (CMS–18F5 and CMS–18F5–SP) was designed to capture all the information needed to make a determination of an individual's entitlement to Part A. This Information Collection Request (ICR) adds the collection instruments SSA uses to collect information from individuals who are filing an Application for Hospital Insurance, updates the burden information. CMS will begin reporting for additional collection instruments, including the internet Claim System (iClaim), Modernized Claims System (MCS), and the Consolidated Claims Experience (CCE). *Form Number:* CMS–18F5 (OMB control number: 0938–0251); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,394,264; *Total Annual Responses:* 1,394,264; *Total Annual Hours:* 348,566. (For policy questions regarding this collection contact Carla Patterson at 410–786–1000.)

Dated: December 1, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–26756 Filed 12–3–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6397]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

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 information collection provisions for calorie labeling of articles of food in vending machines and nutrition labeling of standard menu items in restaurants and similar retail food establishments.

DATES: Submit either electronic or written comments on the collection of information by February 2, 2021.

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 February 2, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 2, 2021. 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–N–6397 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.'' 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, 240–402–7500.

• 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, 240–402–7500.

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.

Food Labeling; Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

OMB Control Number 0910–0782—Extension

This information collection supports FDA regulations under part 101 (21 CFR part 101) and the associated collection instrument Form FDA 3757. The Federal Food, Drug, and Cosmetic Act requires the disclosure of certain calorie labeling of articles of food in vending machines, as well as nutrition information for standard menu items in certain restaurants and retail food establishments. Sections 101.8 and 101.11 provides that respondents with a chain of 20 or more locations will disclose nutritional information of certain foods for consumers of food products for the purpose of making informed dietary choices. We also offer registration for respondents who wish to voluntarily participate with this information collection activity, for which we developed Form FDA 3757 entitled, ''DHHS/FDA Menu and Vending Machine Labeling Voluntary Registration'' to assist respondents in this regard. To keep the registration active, a respondent renews their registration every other year within 60 days prior to the expiration of the respondent's current registration with FDA, or it will automatically expire.

We use the collection of information to help determine compliance with regulatory requirements. Third-party disclosure requirements are used by consumers of food products for the purpose of making informed dietary choices.

Description of Respondents: Respondents to this collection of information are vending machine operators and restaurants or other similar food establishments that are subject to the requirements of part 101 as well as those entities that voluntarily participate with the provisions of this collection of information.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity using form FDA 3757; 21 CFR	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Initial Registration for Vending Machine Labeling; 101.8(d)	13	1	13	2	26
Registration Renewal for Vending Machine Labeling; 101.8(d)	19	1	19	0.5 (30 minutes)	9.5
Initial Registration for Menu Labeling; 101.11(d)	3,559	1	3,559	2	7,118
Registration Renewal for Menu Labeling; 101.11(d)	5,340	1	5,340	0.5 (30 minutes)	2,670
Total					9,823.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Activity; 21 CFR	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record (in hours)	Total hours
Initial Burden (Annualized over 3 years)					
Initial Nutrition Analysis; 101.8(c)(2)(i)(A)	69,017	1	69,017	0.25 (15 minutes)	17,254
Annual Burden					
Recurring Nutrition Analysis; 101.8(c)(2)(i)(A)	30,059	1	30,059	0.25 (15 minutes)	7,515
Total					24,769

[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]

Activity; 21 CFR	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
Calorie Analysis; 101.8(c)(2)(i)	282	11	3,102	1	3,102
Calorie Declaration Signage; 101.8(c)(2)(ii)	3,279	2,122	6,958,038	0.21 (12.5 minutes)	1,461,188
Vending Operator Contact Information; 101.8(e)(1)	3,279	125	409,875	0.025 (1.5 minutes)	10,247
Total					1,474,537

[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.

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26695 Filed 12–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5739]

Formal Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants of Complex Products Under Generic Drug User Fee Amendments; Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is correcting a notice entitled ''Formal Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants of Complex Products Under Generic Drug User Fee Amendments; Guidance for Industry; Availability'' that appeared in the **Federal Register** of November 25, 2020. The document announced the availability for a guidance for industry. The document was published with incorrect information in the Paperwork Reduction Act of 1995 section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 2020 (85 FR 75336), in FR Doc. 2020–26050, the following correction is made:

On page 75337, in the third column, under the heading, ''II. Paperwork Reduction Act of 1995'', the paragraph is corrected to read:

''While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget

(OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for meetings related to generic drug development have been approved under OMB control number 0910–0797.''

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26691 Filed 12–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4739]

Requesting FDA Feedback on Combination Products; Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry and FDA staff entitled ''Requesting FDA Feedback on Combination Products.'' The purpose of this guidance is to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics. These interactions can occur through application-based mechanisms, such as the pre-submission process used in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) and the formal meetings used in the Center for Drug Evaluation and Research (CDER) and CBER, or through Combination Product Agreement Meetings (CPAMs), as appropriate.

DATES: The announcement of the guidance is published in the **Federal Register** on December 4, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2019–D–4739 for ''Requesting FDA Feedback on Combination Products.'' Received comments 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, 240–402–7500.

- 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the to the Office of Combination Products, Food and Drug Administration, Bldg. 32, Rm. 5129, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5125, 301–796–5616, *melissa.burns@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Requesting FDA Feedback on Combination Products.'' The purpose of this guidance is to discuss ways in which combination product sponsors can obtain feedback from the Agency on scientific and regulatory questions. These interactions can occur through application-based mechanisms, such as the pre-submission process used in

CDRH and CBER and the formal meetings used in CDER and CBER, or through CPAMs, as appropriate.

FDA is publishing this guidance consistent with the Agency's ongoing commitment to enhancing clarity and transparency regarding regulatory considerations for combination products, and in accordance with the mandate under section 503(g)(8)(C)(vi) of the Federal Food, Drug, and Cosmetics Act (FD&C Act) (21 U.S.C. 353(g)(8)(C)(vi)), which was added by section 3038 of the 21st Century Cures Act (Pub. L. 114–255). Section 503(g)(8)(C)(vi) of the FD&C Act requires FDA to issue a final guidance addressing: (1) The structured process for managing pre-submission interactions with sponsors developing combination products; (2) best practices to ensure FDA feedback in such pre-submission interactions represents the Agency's best advice based on the information provided during these pre-submission interactions; and (3) how CPAMs relate to other FDA meeting types, what information should be submitted prior to a CPAM, and the form and content of agreements reached through a CPAM.

In response to comments received on the draft guidance, this final guidance includes additional information on use of CPAMs and application-based mechanisms. The guidance also provides additional clarity on how CPAMs will be conducted, including expected timelines for CPAM-related activities.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Requesting FDA Feedback on Combination Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information pertaining to orphan drug provisions in 21 CFR part 316 are approved under OMB control number 0910–0167; the collections of information pertaining to investigational device exemption submission provisions in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information pertaining to investigational new drug submission provisions in 21 CFR part 312 are approved under OMB control number 0910–0014; the collections of information pertaining to biologics licensing submission provisions in 21 CFR part 601 are approved under OMB control number 0910–0338; and the collections of information pertaining to combination product agreement meetings are approved under OMB control number 0910–0523.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents* or *https://www.regulations.gov.*

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26700 Filed 12–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1768]

Advisory Committee; Pharmacy Compounding Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Pharmacy Compounding Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmacy Compounding Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until April 25, 2022.

DATES: Authority for the Pharmacy Compounding Advisory Committee will expire on April 25, 2022, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *PCAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3, FDA is announcing the renewal of the Pharmacy Compounding Advisory Committee (Committee). The Committee is a non-discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to compounding drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee shall provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility and make appropriate recommendations to the Commissioner of Food and Drugs.

Pursuant to its Charter, the Committee shall consist of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one or more technically qualified members, selected by the Commissioner or designee, who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one or more non-voting representative members who are identified with industry interests. There

may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/pharmacy-compounding-advisory-committee/pharmacy-compounding-advisory-committee-charter* or by contacting the Designated Federal Officer (see FOR FURTHER INFORMATION CONTACT). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26696 Filed 12–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2216]

Revocation of Authorizations of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocations of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Manufacturers of Protective Barrier Enclosures and Other Stakeholders for certain protective barrier enclosures (''PBE Authorization'') and to Manufacturers of Infusion Pumps and Infusion Pump Accessories and Other Stakeholders for certain infusion pumps and infusion pump accessories (''Infusion Pump Authorization''). FDA revoked the PBE Authorization on August 20, 2020, and the Infusion Pump Authorization on September 21, 2020, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The PBE Authorization is revoked as of August 20, 2020. The Infusion Pump Authorization is revoked as of September 21, 2020.

ADDRESSES: Submit written requests for single copies of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On May 1, 2020, FDA issued the PBE Authorization. On May 13, 2020, FDA issued the Infusion Pump Authorization. Of note, these were both ''umbrella'' Authorizations, *i.e.,* for certain types of products that met the requirements as described in their respective Authorizations. Any product with an individual Authorization is not affected by revocation of these two umbrella Authorizations. Notice of the issuance of the Authorizations was published in the **Federal Register** on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. Subsequent to the issuance of the PBE Authorization, FDA considered new information, specifically from new preliminary evidence from simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure. Subsequent to the issuance of the Infusion Pump Authorization, FDA considered that no device had been listed under the EUA and that circumstances instead support allowing for tailored requirements of authorization in individual EUAs.

II. EUA Criteria for Issuance No Longer Met and Other Circumstances Make Revocation Appropriate To Protect the Public Health or Safety

Under section 564(g)(2)(B) and (C) of the FD&C Act, the Secretary of the Department of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety. On August 20, 2020, FDA revoked the PBE Authorization because the criteria for issuance were no longer met and other circumstances make such revocation appropriate to protect the public health or safety. Under section 564(c)(2) of the FD&C Act, an EUA may be issued only if FDA concludes that, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing such disease or condition and that the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product.

Given the new preliminary evidence from simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure recently reported in literature articles, FDA has concluded it is not reasonable to believe the product may be effective in decreasing healthcare provider exposure to airborne particles and may instead contribute to an increase in healthcare provider exposure to airborne particles. Additionally, the literature articles note potential risks of protective barrier enclosures, such as increased intubation times, lower first-pass intubation success rates, damage to personal protective equipment from intubation boxes, particles escaping from intubation boxes through arm access holes reaching the face of the healthcare provider performing the endotracheal intubation, and human factors issues contributing to increased endotracheal intubation times. Further, based on the same information and the risks to public health, including from the device's potential contribution to an increase in healthcare provider exposure to airborne particles, FDA has concluded under section 564(g)(2)(C) of the FD&C Act that other circumstances make revocation appropriate to protect the public health or safety. Accordingly, FDA has revoked the PBE

Authorization, pursuant to section 564(g)(2)(B) and (C) of the FD&C Act.

On September 21, 2020, FDA revoked the Infusion Pump Authorization because other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act), considering that no device has been listed under the EUA, and circumstances instead support allowing for tailored requirements of authorization in individual EUAs.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov,* and *https://www.fda.gov/media/142374/download* and *https://www.fda.gov/media/141415/download.*

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g) of the FD&C Act are met, FDA has revoked the EUAs for certain protective barrier enclosures and certain infusion pumps and infusion pump accessories. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

August 20, 2020

To: Manufacturers of Protective Barrier Enclosures;
Health Care Providers;
Hospital Purchasing Departments and Distributors; and
Any Other Stakeholders

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) issued May 1, 2020, for emergency use of protective barrier enclosures[1] by healthcare providers (HCP)[2] when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment (PPE).

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

Since issuance of the May 1, 2020 umbrella EUA, FDA has become aware of information that supports a determination to revoke the umbrella EUA on the grounds that the criteria under section 564(c) of the Act for issuance of an EUA are no longer met (see section 564(g)(2)(B)). Under section 564(c) of the Act, an EUA may be issued only if FDA concludes "that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing ---(i) such disease or condition [...]; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product [...]."

[1] A protective barrier enclosure is a transparent device designed to cover a patient's head and upper body that incorporates one or more ports through which the HCP's hands are passed to perform medical procedures. The authorized protective barrier enclosures were passive—they did not include fans, air filters, or other features and were not intended to generate negative pressure. The authorized Protective Barrier Enclosures were intended to be used as a physical barrier by HCPs in situations including, but not limited to, airway management (e.g., intubation, extubation, and suctioning of airways) and any aerosol generating procedures (e.g., nebulizer treatments, manipulation of oxygen mask or Bilevel Positive Airway Pressure (BiPAP) mask). These products were intended to provide an additional layer of barrier protection in addition to Personal Protective Equipment (PPE) against airborne particles or droplets from the patients. These products were not intended to replace the need for PPE.

[2] For the EUA, HCP referred to practitioners, including physicians, nurses, pharmacists, dentists, respiratory therapists, physical therapists, technologists, or any other practitioners or allied health professionals that have a role in using a device for human use.

In addition, FDA has determined that revocation is appropriate to protect the public health or safety (see section 564(g)(2)(C) of the Act), and that individualized consideration of each EUA request for protective barrier enclosures would better protect the public health.

Specifically, FDA has become aware of new preliminary evidence from simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure recently reported in the literature.[3,4] Overall, these literature articles provide new evidence that protective barrier devices covered under the umbrella EUA may not be effective in decreasing HCP exposure to airborne particles and may instead contribute to an increase in HCP exposure to airborne particles. Additionally, the articles note potential risks of protective barrier enclosures, such as increased intubation times, lower first-pass intubation success rates, damage to PPE from intubation boxes, particles escaping from intubation boxes through arm access holes reaching the face of the HCP performing the endotracheal intubation, and human factors issues contributing to increased endotracheal intubation times.

After reviewing the totality of the data and information received by FDA since issuance of the May 1, 2020, EUA, FDA has determined that revocation of the umbrella EUA for protective barrier enclosures is appropriate. FDA believes it is no longer reasonable to believe that the authorized protective barrier enclosures may be effective at preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 in healthcare settings, and FDA can no longer conclude that the known and potential benefits of protective barrier enclosures, for such use, outweigh the known and potential risks of such product; thus, the criteria under section 564(c) of the Act for issuance of an EUA are no longer met. In addition, based on the risks identified in the currently available data and information, including the device's potential contribution to an increase in HCP exposure to airborne particles, FDA has concluded that revocation of the EUA is appropriate to protect the public health or safety, and that individualized consideration of each EUA request for protective barrier enclosures would better protect the public health.

Accordingly, pursuant to section 564(g)(2)(B)&(C) of the Act, FDA revokes the EUA issued on May 1, 2020.

The devices covered by the May 1, 2020 EUA are not approved or authorized by FDA for any indication and therefore cannot be legally introduced into interstate commerce. In addition, under section 564(f)(2) of the Act, devices that were distributed under this EUA remain authorized for emergency use to continue to prevent HCP exposure to pathogenic biological particulates when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 for which the authorized product has already been administered prior to the date of revocation, to the extent found necessary by such patient's attending physician.

---

[3] Simpson J.P., et al. Measurement of airborne particle exposure during simulated tracheal intubation using various proposed aerosol containment devices during the COVID-19 pandemic. Anesthesia, 19 June 2020, 1-9.
[4] Begley J.I., et al. The Aerosol box for intubation in COVID-19 patients: an in-situ simulation crossover study. Anesthesia, August 2020. 75 (8), 1014-1021.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

September 21, 2020

To Manufacturers and Other Stakeholders:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA) issued May 13, 2020, for emergency use of infusion pumps and infusion pump accessories[1] for use by healthcare providers (HCPs) to treat conditions caused by the Coronavirus Disease 2019 (COVID-19) with the controlled infusion of medications, total parenteral nutrition (TPN), and/or other fluids.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that circumstances make revocation of this EUA appropriate to protect the public health or safety. Any infusion pumps and infusion pump accessories added to the list of authorized devices in Appendix A of the May 13, 2020, letter of authorization would have been authorized for use by HCPs to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids. This includes infusion pumps with remote monitoring or remote manual control features or administration sets and other accessories with increased length that help maintain a safe physical distance between HCPs and patients with confirmed or suspected COVID-19 to reduce HCP exposure to the virus that causes COVID-19. To date, no device has been listed in Appendix A.

Based on information and experience since issuance of the umbrella EUA, FDA has determined that circumstances support revocation of the umbrella EUA. Individual EUAs will allow for tailored indications and scopes of authorization, including but not limited to those for different environments of use, routes of administration, and patient populations. In addition, this would allow for individualized conditions of authorization to address any issue unique to a specific device, and more streamlined EUA amendments, such as additional uses that would not fall under this umbrella EUA. Accordingly, FDA has decided to revoke this EUA. Instead, FDA

[1] The infusion pumps authorized under the EUA had to fall within the scope of devices and meet the safety, performance, and labeling criteria set forth in the EUA. Regarding scope, infusion pumps had to pump fluids, including medications, total parenteral nutrition (TPN), and/or other fluids, into a patient in a controlled manner. The "authorized devices" included those that may use a piston pump, roller pump, a peristaltic pump, or other pumping mechanism and those that may be powered electrically or mechanically. The EUA also authorized use of infusion pumps accessories intended to support, supplement, and/or augment the performance of infusion pumps, including those that may include intravenous administration sets, stopcocks, and different catheters.

Page 2 – Infusion Pumps and Infusion Pump Accessories

may issue individual EUAs for infusion pumps and infusion pump accessories that meet the requisite EUA statutory criteria.

FDA has determined that circumstances make revocation of this EUA appropriate to protect the public health or safety for purposes of section 564(g)(2)(C) of the Act.

Accordingly, pursuant to section 564(g)(2) of the Act, FDA revokes the EUA issued on May 13, 2020.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

BILLING CODE 4164–01–C

Dated: November 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26697 Filed 12–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Appointment to the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS), Office of Minority Health (OMH) is seeking nominations of qualified candidates to be considered for appointment as a member of the Advisory Committee on Minority Health (hereafter referred to as the ''Committee or ACMH''). The Committee provides advice to the Deputy Assistant Secretary for Minority Health on the development of goals and specific program activities for improving the health and the quality of health care minorities receive and eliminating racial and ethnic health disparities consistent with the Public Health Service (PHS) Act.

DATES: Nominations for membership on the Committee must be received no later than 5:00 p.m. EST on March 4, 2021, at the address listed below.

ADDRESSES: All nominations should be emailed to CAPT Samuel Wu, Designated Federal Officer, Advisory Committee on Minority Health, Office of Minority Health, at *SAMUEL.WU@hhs.gov* and copy to *OMH-ACMH@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: CAPT Samuel Wu, Designated Federal Officer, Advisory Committee on Minority Health, Office of Minority Health, Department of Health and Human Services. Phone: 240–453–6173; email: *SAMUEL.WU@hhs.gov.*

A copy of the ACMH charter and list of the current Committee membership can be obtained by contacting CAPT Wu or by accessing the website managed by OMH at *www.minorityhealth.hhs.gov.* Information about ACMH activities also can be found on the OMH website under the heading, About OMH, Committees and Working Groups.

SUPPLEMENTARY INFORMATION: Pursuant to Public Law 105–392, the HHS Secretary established the ACMH. The Committee provides advice to the Deputy Assistant Secretary for Minority Health on the development of goals and specific program activities for improving the health and the quality of health care minorities receive and eliminating racial and ethnic health disparities consistent with Section 1707 of PHS Act, 42 U.S.C. 300u—6. Management and support services for the ACMH are provided by OMH.

Nominations: The Committee is composed of 12 voting members. The Committee composition also can include non-voting *ex officio* members. This announcement is seeking nominations for voting members. Voting members of the Committee are appointed by the Secretary from individuals who are not officers or employees of the federal government and who have expertise regarding issues of minority health. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise working on issues impacting the health of racial and ethnic minority populations. The Committee charter stipulates that health interests of the racial and ethnic minority groups shall be equally represented on the Committee: Hispanics/Latinos, African Americans, American Indians/Alaska Natives, and Asian Americans and Pacific Islanders (AAPI).

There will be six vacancies on the Committee by early 2021: Three vacancies representing American Indian/Alaska Native population, one vacancy representing Hispanic/Latino population, and two vacancies representing AAPI populations. OMH is particularly seeking nominations for individuals who can represent the health interests of these racial and ethnic minority groups.

Mandatory Professional/Technical Qualifications: Nominees must meet all of the following mandatory qualifications to be eligible for consideration:

(1) Expertise in minority health and racial and ethnic health disparities;

(2) Expertise in developing or contributing to the development of science-based or evidence- based health

policies and/or programs. This expertise may include experience in the analysis, evaluation, and interpretation of federal/state health or regulatory policy;

(3) Involvement in national, state, regional, tribal, and/or local efforts to improve the health status or outcomes among racial and ethnic minority populations;

(4) Educational achievement, professional certification(s) in health-related fields (*e.g.,* health professions, allied health, behavioral health, public health, health policy and health administration/management), and professional experience that will support the ability to give expert advice on issues related to improving minority health and eliminating racial and ethnic health disparities; and

(5) Expertise in population level health data for racial and ethnic minority groups (*e.g.,* survey, administrative, and/or clinical data).

Desirable Qualifications:

(1) Knowledge and experience in health care systems, cultural and linguistic competency, social determinants of health, evidence-based research, data collection (*e.g.,* federal, state, tribal, or local data collection), or health promotion and disease prevention; and

(2) Nationally recognized via peer-reviewed publications, professional awards, advanced credentials, or involvement in national professional organizations.

Requirements for Nomination Submission: Nominations should be typewritten (one nomination per nominator). Nomination package should include: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee indicating a willingness to serve as a member of the Committee; (2) the nominee's contact information, including name, mailing address, telephone number, and email address; (3) the nominee's current curriculum vitae which should not exceed 10 pages; and (4) a summary of the nominee's experience and qualification relative to the mandatory professional and technical criteria listed above. Federal employees should not be nominated for consideration of appointment to this Committee.

Individuals selected for appointment to the Committee shall be invited to serve a four-year term. Committee members will receive a stipend for attending Committee meetings and conducting other business in the interest of the Committee, including per diem and reimbursement for travel expenses incurred.

The Department makes every effort to ensure that the membership of an HHS federal advisory committee is fairly balanced in terms of points of view represented to support the committee's function. Every effort is made to ensure a broad representation of individuals are considered for membership on HHS federal advisory committees, including considerations of geographic diversity, gender, racial and ethnic and minority groups, and people with disabilities. Appointment to this Committee shall be made without discrimination because of a person's race, color, religion, sex (including pregnancy), national origin, age, disability, or genetic information. Nominations must state that the nominee is willing to serve as a member of ACMH and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee; therefore, individuals selected for nomination will be required to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

Individuals selected to serve on the ACMH through the nomination process will be posted on the OMH website once selections have been made.

Authority: 42 U.S.C. 300u–6, Section 1707 of the Public Health Service Act, as amended. The Advisory Committee is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: November 24, 2020.

Samuel Wu,

CAPT, U.S. Public Health Service, Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2020–26641 Filed 12–3–20; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV–2) and Coronavirus Disease 2019 (COVID–19).

Date: December 28–29, 2020.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E70, Rockville, MD 20892, (Virtual Meeting).

Contact Person: Mohammed S. Aiyegbo, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E70, Rockville, MD 20852, (301) 761–7106, *mohammed.aiyegbo@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 1, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–26751 Filed 12–3–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Diet and Aging.

Date: January 15, 2021.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Video Meeting).

Contact Person: Anita H. Undale, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 827–7428, *anita.undale@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 1, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–26752 Filed 12–3–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2020–0035]

Privacy Act of 1974; Computer Matching Program

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: Notice of a re-established matching program.

SUMMARY: As required by the Privacy Act of 1974, as amended, DHS/USCIS is issuing public notice of the re-established computer matching program between DHS, USCIS and the California Department of Social Services (CA–DSS), titled ''Verification Division DHS–USCIS/CA–DSS.''

DATES: This re-established matching program will commence not sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. This matching program will be conducted for an initial term of 18 months (from approximately January 28, 2021 to July 27, 2022) and within 3 months of expiration may be renewed for one additional year if the parties make no substantive change to the matching program and certify that the program has been conducted in compliance with the matching agreement.

ADDRESSES: You may submit comments, identified by docket number DHS–2020–0035, at:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.
- *Mail and hand delivery or commercial delivery:* U.S. Citizenship and Immigration Services, ATTN: Privacy Officer—Donald K. Hawkins, 20 Massachusetts Avenue NW, Washington, DC 20529.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and docket number DHS–2020–0035. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: DHS Privacy Office Chief Privacy Officer Constantina Kozanas at 202–343–1717.

SUPPLEMENTARY INFORMATION: The DHS–USCIS provides this notice in accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503) and the Computer Matching and Privacy Protection Amendments of 1990 (Pub. L. 101–508) (Privacy Act); Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular A–108, 81 FR 94424 (December 23, 2016).

Participating Agencies

The Department of Homeland Security, U.S. Citizenship and Immigration Services (DHS–USCIS) is the source agency and the California Department of Social Services (CA–DSS) is the recipient agency.

Authority for Conducting the Matching Program

Section 121 of the Immigration Reform and Control Act (IRCA) of 1986, Pub. Law No. 99–603, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), Pub. Law No. 104–193, 110 Stat. 2168 (1996), requires DHS to establish a system for the verification of immigration status of alien applicants for, or recipients of, certain types of benefits as specified within IRCA, and to make this system available to state agencies that administer such benefits. Section 121(c) of IRCA amends Section 1137 of the Social Security Act and certain other sections of law that pertain to federal entitlement benefit programs. Section 121(c) requires state agencies administering these programs to use DHS–USCIS's verification system to make eligibility determinations in order to prevent the issuance of benefits to ineligible alien applicants. The Verification Information System (VIS) used by the DHS/USCIS Systematic Alien Verification for Entitlements (SAVE) Program is the DHS–USCIS system available to the CA–DSS and other covered agencies for use in making these eligibility determinations.

The Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), Public Law 104–208, 110 Stat. 3009 (1996) grants federal, state, or local government agencies seeking to verify or ascertain the citizenship or immigration status of any individual within the jurisdiction of the agency with the authority to request such information from DHS–USCIS for any purpose authorized by law, and to send information related to immigration status information to DHS–USCIS, notwithstanding any other provision of law.

CA–DSS will access information contained in the SAVE Program for the purpose of confirming the immigration status of alien applicants for, or recipients of, benefits it administers to discharge its obligation to conduct such verifications pursuant to Section 1137 of the Social Security Act (42 U.S.C. 1320b-7(a) *et seq.*), Section 213A of the Immigration and Nationality Act (8 U.S.C. 1183a and 1631), and California Welfare and Institution Codes 11104.1, 14007.5 and 14011.2.

Purpose(s)

The purpose of this Agreement is to re-establish the terms and conditions governing CA–DSS's access to, and use of, the DHS–USCIS Systematic Alien Verification for Entitlements (SAVE) Program, which provides immigration status information from federal immigration records to authorized users, and to comply with the Computer Matching and Privacy Protections Act of 1988.

CA–DSS will use the SAVE Program to verify the immigration status of non-U.S. citizens who apply for federal benefits (Benefit Applicants) under Temporary Assistance to Needy Families (TANF) and Supplemental Nutrition Assistance Program (SNAP) programs that CA–DSS administers. CA–DSS will use the information obtained through the SAVE Program to determine whether Benefit Applicants possess the requisite immigration status to be eligible for the TANF and SNAP programs administered by CA–DSS.

Categories of Individuals

DHS–USCIS will provide the following to CA–DSS: Records in DHS–USCIS VIS and SAVE Program containing information related to the status of aliens and other persons on whom DHS–USCIS has a record as an applicant, petitioner, or beneficiary.

CA–DSS will provide the following to DHS–USCIS: CA–DSS records pertaining to alien and naturalized/derived United States citizen applicants for, or recipients of, entitlement benefit programs administered by the State.

Categories of Records

Data elements contained within CA–DSS records that may be matched with federal immigration records during automated initial verification or additional verification include the following: Full name; Date of Birth; One or More Immigration Number (*e.g.* Alien Registration USCIS Number; Arrival Departure Record (I–94 Number); SEVIS ID Number; Certificate of Naturalization Number; Certificate of Citizenship Number, or Unexpired Passport Number); and, Other information from Immigration Documentation (*e.g.* Country of Birth, Date of Entry, Employment Authorization Category).

Data elements contained within DHS–USCIS's records to be provided to CA–DSS may consist of the following: Full name; Date of Birth; one or more Immigration Number (*e.g.* Alien Registration USCIS Number; Arrival Departure Record (I–94 Number); SEVIS ID Number; Certificate of Naturalization Number, Certificate of Citizenship Number, or Unexpired Passport Number); Other information from Immigration Documentation (*e.g.* Country of Birth; Date of Entry; Employment Authorization Category); Sponsorship Data (*e.g.* name, address, and social security number of FORM I–864/I–864EZ sponsors and Form I–864A household members, when applicable); and Case Verification Number.

System of Records

DHS/USCIS–004 Systematic Alien Verification for Entitlements (SAVE) Systems of Records Notice, 85 FR 31798 (May 27, 2020).

Constantina Kozanas,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2020–26699 Filed 12–3–20; 8:45 am]

BILLING CODE 9110–9L–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2020–0124; FXES11140300000–201]

Draft Environmental Assessment and Proposed Habitat Conservation Plan; Receipt of an Application for an Incidental Take Permit, Meadow Lake Wind Resource Area, White and Benton Counties, Indiana

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment and information.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application from six wholly owned subsidiaries of EDP Renewables North America LLC collectively known as Meadow Lake Group (applicant) for an incidental take permit (ITP) under the Endangered Species Act, for its Meadow Lake Wind Resource Area wind project. If approved, the ITP would be for a 29-year period and would authorize the incidental take of the Indiana bat and the northern long-eared bat. The applicant has prepared a habitat conservation plan (HCP) that describes the actions and measures that the applicant would implement to avoid, minimize, and mitigate incidental take of the species. We also announce the availability of a draft environmental assessment (DEA), which has been prepared in response to the permit application in accordance with the requirements of the National Environmental Policy Act. We request public comment on the application and associated documents.

DATES: We will accept comments received or postmarked on or before January 4, 2021.

ADDRESSES: *Document availability:* Electronic copies of the documents this notice announces, as well as public comments we receive, will be available online in Docket No. FWS–R3–ES–2020–0124 at *http://www.regulations.gov.*

Comment submission: In your comment, please specify whether your comment addresses the proposed HCP, draft EA, or any combination of the aforementioned documents, or other supporting documents. You may submit written comments by one of the following methods:

- *Online: http://www.regulations.gov.* Search for and submit comments on Docket No. FWS–R3–ES–2020–0124.
- *By hard copy:* Submit comments by U.S. mail to Public Comments Processing, Attn: Docket No. FWS–R3–ES–2020–0124; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS: PRB/3W; Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Scott Pruitt, Field Supervisor, Bloomington Ecological Services Field Office, U.S. Fish and Wildlife Service, 620 South Walker Street, Bloomington, IN 47403; telephone: 812–334–4261, extension 214; or Andrew Horton, Regional HCP Coordinator, U.S. Fish and Wildlife Service—Interior Region 3, 5600 American Blvd., West, Suite 990, Bloomington, MN 55437–1458; telephone: 612–713–5337.

Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have received an application from EDP Renewables' Meadow Lake Group (applicant) for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), for its Meadow Lake Resource Area (project or MLWRA). The MLWRA consists of 414 turbines that are owned by six companies: Meadow Lake Wind Farm LLC, Meadow Lake Wind Farm II LLC, Meadow Lake Wind Farm III LLC, Meadow Lake Wind Farm IV LLC, Meadow Lake Wind Farm V LLC, and Meadow Lake Wind Farm VI LLC. If approved, the ITP would be for a 29-year period and would authorize the incidental take of an endangered species, the Indiana bat (*Myotis sodalis*), and a threatened species, the northern long-eared bat (*Myotis septentrionalis*). The applicant has prepared a habitat conservation plan (HCP) that describes the actions and measures that the applicant would implement to avoid, minimize, and mitigate incidental take of the Indiana bat and northern long-eared bat. We also announce the availability of a draft environmental assessment (DEA), which has been prepared in response to the permit application in accordance with the requirements of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*). We request public comment on the application and associated documents.

Background

Section 9 of the ESA and its implementing regulations prohibit the ''take'' of animal species listed as endangered or threatened. Take is defined under the ESA as to ''harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect ''listed animal species,'' or to attempt to engage in such conduct'' (16 U.S.C. 1538). However,

under section 10(a) of the ESA, we may issue permits to authorize incidental take of listed species. ''Incidental take'' is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for endangered and threatened species, respectively, are found in the Code of Federal Regulations at 50 CFR 17.22 and 50 CFR 17.32.

Applicant's Proposed Project

The applicant requests a 29-year ITP to take the federally endangered Indiana bat (*Myotis sodalis*) and threatened northern long-eared bat (*Myotis septentrionalis*). The applicant determined that unavoidable take is reasonably certain to occur incidental to operation of 414 previously constructed wind turbines. The proposed conservation strategy in the applicant's proposed HCP is designed to avoid, minimize, and mitigate the impacts of the covered activity on the covered species. The biological goals and objectives are to minimize potential take of Indiana bats and northern long-eared bats through on-site minimization measures and to provide habitat conservation measures for Indiana bats and northern long-eared bats to offset any impacts from operations of the project. The HCP provides on-site avoidance and minimization measures, which include turbine operational adjustments. The estimated level of take from the project is 728 Indiana bats and 169 northern long-eared bats over the 29-year project duration. To offset the impacts of the taking of Indiana bats and northern long-eared bats, the applicant proposes mitigation that will consist of one or more of the following: Protection of a hibernaculum, protection of summer maternity colony habitat, restoration of summer maternity colony habitat, and protection of swarming habitat.

National Environmental Policy Act

The issuance of an ITP is a Federal action that triggers the need for compliance with NEPA. We prepared a draft EA that analyzes the environmental impacts on the human environment resulting from three alternatives: A no-action alternative, the proposed action, and a more restrictive alternative consisting of feathering at a rate of wind speed that results in less impacts to bats.

Next Steps

The Service will evaluate the permit application and the comments received to determine whether the application meets the requirements of section 10(a) of the ESA. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the above findings, we will determine whether the permit issuance criteria of section 10(a)(l)(B) of the ESA have been met. If met, the Service will issue the requested ITP to the applicant.

Request for Public Comments

The Service invites comments and suggestions from all interested parties during a 30-day public comment period (see **DATES**). In particular, information and comments regarding the following topics are requested:

1. The direct, indirect, or cumulative effects that implementation of any alternative could have on the human environment;
2. Whether or not the significance of the impact on various aspects of the human environment has been adequately analyzed; and
3. Any other information pertinent to evaluating the effects of the proposed action on the human environment.

Because this permit application was sufficiently complete prior to the effective date of the new NEPA regulations, we are exercising our discretion to conduct our NEPA analysis under the regulations in effect prior to September 14, 2020.

Availability of Public Comments

You may submit comments by one of the methods shown under **ADDRESSES**. We will post on *http://regulations.gov* all public comments and information received electronically or via hardcopy. All comments received, including names and addresses, will become part of the administrative record associated with this action. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22) and the NEPA (42 U.S.C. 4371 *et seq.*) and its implementing regulations (40 CFR 1506.6 (2019); 43 CFR part 46).

Lori Nordstrom,

Assistant Regional Director, Ecological Services.

[FR Doc. 2020–26667 Filed 12–3–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

[RR04900000, 200R0680R1, RR.17549897.2020000.01]

Notice of Contract Execution Between the Central Utah Water Conservancy District (District) and Department of the Interior (Interior) for Prepayment of Costs Allocated to Municipal and Industrial Water from the Bonneville Unit of the Central Utah Project, Utah County, Utah

AGENCY: Office of the Assistant Secretary for Water and Science, Interior.

ACTION: Notice of contract execution.

SUMMARY: On October 1, 2020, Block Notice 7A–2 was issued to the District for 22,000 acre-feet of Municipal and Industrial water from the Utah Lake Drainage Basin Water Delivery System, Bonneville Unit of the Central Utah Project. Subsequently, on October 28, 2020, Interior and the District entered into a contract for the District to prepay the repayment obligation associated with Block Notice 7A–2.

FOR FURTHER INFORMATION CONTACT: Additional information on matters related to this **Federal Register** notice can be obtained by contacting Mr. Lee Baxter, Senior Program Coordinator, Central Utah Project Completion Act Office, Department of the Interior, 302 East Lakeview Parkway, Provo, Utah 84606; via telephone at (801) 379–1174; or by email at *lbaxter@usbr.gov.*

SUPPLEMENTARY INFORMATION: Public Law 102–575, Central Utah Project Completion Act, Section 210, as amended through Public Law 104–286, stipulates that ''the Secretary shall allow for prepayment of the repayment contract between the United States and the Central Utah Water Conservancy District (District) dated December 28, 1965, and supplemented on November 26, 1985, or any additional or supplemental repayment contract providing for repayment of municipal and industrial water delivery facilities of the Central Utah Project for which repayment is provided pursuant to such contract, under terms and conditions

similar to those contained in the supplemental contract that provided for the prepayment of the Jordan Aqueduct dated October 28, 1993. The prepayment may be provided in several installments to reflect substantial completion of the delivery facilities being prepaid and may not be adjusted on the basis of the type of prepayment financing utilized by the District.''

In accordance with Public Law 102–575, the District prepaid the municipal and industrial repayment obligation associated with Block Notice 7A–2 from the Utah Lake Drainage Basin Water Delivery System, a component of the Bonneville Unit of the Central Utah Project. The terms of the prepayment were publicly negotiated between the District and Interior on September 23, 2020.

Reed R. Murray,

Program Director,Central Utah Project Completion Act Office, Department of the Interior.

[FR Doc. 2020–26738 Filed 12–3–20; 8:45 am]

BILLING CODE 4332–90–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[DOI–BLM–NV–W010–2020–0012–EIS; LLNVW00000.L51100000.GN0000. LVEMF1907180.19X .MO# 4500149816]

Notice of Availability of the Final Environmental Impact Statement for the Proposed Thacker Pass Project, Two Plans of Operations Submitted by Lithium Nevada Corporation for Mining and Exploration in Humboldt County, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) Humboldt River Field Office, Winnemucca, Nevada, as the lead agency, has prepared the Thacker Pass Lithium Mine Project Final Environmental Impact Statement (EIS), for the proposed Lithium Mine Project Proposed Plans of Operations and Reclamation Plan Permit Applications (the Project) in Humboldt County, Nevada, and by this notice announces the availability of the FEIS. In accordance with the Bald and Golden Eagle Protection Act (Eagle Act), the Fish and Wildlife Service (FWS) is a cooperating agency with the BLM on the development of this FEIS and has used it to analyze the potential impacts of approving LNC's request for an incidental take permit for golden eagles. FWS has evaluated the LNC's Eagle Conservation Plan (ECP), which describes their request for incidental take of eagles and a 5-year incidental take permit for golden eagles under the Eagle Act.

DATES: The BLM will not issue a final decision on the proposal for a minimum of 30 days after the Environmental Protection Agency publishes its notice of availability of the Thacker Pass Lithium Mine Project Final EIS DOI–BLM–NV–W010–2020–0012–EIS in the **Federal Register**. BLM will coordinate with the FWS on impacts to golden eagles and the Eagle Act permitting process prior to signing a Record of Decision.

ADDRESSES: Copies of North-South Exploration and the Thacker Pass Mine Plans of Operations and the Thacker Pass Project Final EIS are available for public inspection on the internet at *https://bit.ly/2Npgf9l.*

FOR FURTHER INFORMATION CONTACT: For questions about the proposed Project contact Mr. Ken Loda, Lead Geologist, Bureau of Land Management Humboldt River Field Office telephone: (775) 623–1500, address: 5100 East Winnemucca Boulevard, Winnemucca, Nevada 89445. For questions concerning the Eagle Act permitting process, contact Mr. Thomas Leeman, Deputy Chief, Migratory Bird Program, U.S. Fish and Wildlife Service, Department of the Interior Region 10, at (916) 978–6189. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact either of the above individuals during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with either one of the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The applicant, LNC proposes to construct, operate, reclaim, and eventually close an open pit lithium mine, processing operation, and continued exploration activities (the Project), on public lands in northern Humboldt County, Nevada.

LNC currently has two approved Plans of Operation, one for exploration and one for a specialty clay mine, approved within the area proposed for the new lithium mine. There are 75 acres of exploration disturbance approved under LNC's existing exploration Plan, and 140 acres of existing disturbance approved under their clay mine Plan.

LNC has submitted two new Plans of Operations to develop the Project and to provide a description of the proposed lithium mining, processing, and exploration operations. Each of these new Plans of Operation include a reclamation plan for the activities identified under its respective Plan of Operation. The operations proposed under the two new Plans of Operation would involve a project area of about 18,000 acres, with an ultimate disturbance footprint of approximately 5,700 acres. The new lithium mine Plan of Operation boundary overlaps the existing approved Plan boundaries.

LNC proposes to develop the Project in two phases over the estimated 41-year mine life. Pending LNC receiving the required authorizations and permits for Phase 1 of the Project, pre-stripping would commence in early 2021, and construction in the first quarter of 2021, with mining production and ore processing estimated to commence in late 2022. LNC estimates that it would complete mining, processing, and concurrent reclamation activities in 2061, after which, reclamation, site closure activities, and post-closure monitoring would occur for a minimum of five years.

The proposed activities and facilities associated with the Project include development of an open pit mine, construction and operation of lithium processing and production facilities, mine facilities to support mining operations, two waste rock storage facilities, a run-of-mine stockpile, a clay tailings filter stack, water supply facilities, two power transmission lines and substations, and various ancillary facilities. Pit dewatering is not expected to be required as part of the Project until 2055, and concurrent backfill of the open pit would occur after sufficient volume has been excavated to initiate direct placement of waste rock. Exploration would be conducted under both new Plans. In addition, the Project would affect golden eagle nests and territories by planned blasting within a two-mile radius of golden eagle nests; therefore, LNC has requested authorization from the FWS to disturb eagle nests and a 5-year incidental take permit for golden eagles under the Eagle Act. The permit application includes an Eagle Conservation Plan, which contains commitments to avoid, minimize, and mitigate adverse effects on golden eagles resulting from the implementation of the Project. Issuance of an eagle take permit must comply with the Eagle Act and all related regulatory requirements (50 CFR 22.26).

The Final EIS describes and analyzes the proposed Project's direct, indirect,

and cumulative impacts on all affected resources. In addition to the Proposed Action, Alternative A, the following alternatives are also analyzed in the document: Alternative B, which is a partial backfilling of the pit that would result in a small wet area; Alternative C which does not backfill the pit and would result in three small, and probably seasonal, pit lakes; and the No Action Alternative. Alternatives A, B and C include an application for an eagle take permit for loss of productivity of three golden eagle breeding pairs. Additionally, Alternative C would require nest site enhancement as compensatory mitigation under the Bald and Golden Eagle Protection Act.

A Notice of Availability (NOA) of the Draft Environmental Impact Statement (EIS) for the proposed Project was published in the **Federal Register** on July 31, 2020 (85 FR 10460). Two virtual public meetings were held during the comment period. The BLM received 63 public comment documents during the 45-day comment period. The documents contained 813 individual substantive comments which included concerns on potential impacts to groundwater quality, potential impacts to springs and stream flows in the surrounding area of the mine, storage and management of waste rock and tailings, grazing allotments, and mine closure. These comments were considered and addressed in Appendix R (Comments Responses) of the Final EIS.

Comments on the Draft EIS received from the public and internal BLM review were considered and incorporated, as appropriate, into the Final EIS. Public comments resulted in corrections or the addition of clarifying text but did not significantly change the proposed action.

The BLM has consulted with the Nevada State Historic Preservation Office (SHPO) on the Project in accordance with the 2014 State Protocol Agreement between the BLM and Nevada SHPO for Implementing the National Historic Preservation Act. The BLM has determined that the Project would cause adverse effects to 57 historic properties and the Nevada SHPO has concurred. The BLM and Nevada SHPO recently executed a Memorandum of Agreement to resolve adverse effects to the 57 historic properties. The specific actions necessary to resolve adverse effects to historic properties would be carried out if the Project is authorized, prior to Project implementation.

The BLM has consulted and continues to consult with Indian tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies. Tribal concerns, including impacts to Indian trust assets and potential impacts to cultural resources have been analyzed in the Final EIS.

(Authority: 40 CFR 1506.6 and 43 CFR 1506.10)

Ester M. McCullough,

Winnemucca District Manager.

[FR Doc. 2020–26599 Filed 12–3–20; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[21X.LLAK930000 L16100000.PN0000]

Notice of Availability of the Proposed Resource Management Plan and Final Environmental Impact Statement for the Bering Sea-Western Interior Planning Area, Alaska

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), Anchorage Field Office, Anchorage, Alaska, prepared a Proposed Resource Management Plan (RMP)/Final Environmental Impact Statement (EIS) for the Bering Sea–Western Interior region of Alaska and by this notice is announcing its availability.

DATES: BLM planning regulations state that any person who meets the conditions as described in the regulations at 43 CFR 1610.5–2 may protest the BLM's Proposed RMP/Final EIS. A person who meets the conditions must file or postmark their protest no later than 30 days from the date of the Final EIS Notice of Availability published by the Environmental Protection Agency.

ADDRESSES: Copies or notification of the electronic availability of the RMP for the Bering Sea–Western Interior Proposed RMP/Final EIS are being sent to affected federal, State, tribal, and local government agencies and to other stakeholders. The electronic Proposed RMP/Final EIS is available on the BLM's National Environmental Policy Act (NEPA) Register (*https://eplanning.blm.gov/eplanning-ui/project/36665/510* [please use Chrome]) and at *https://www.blm.gov/programs/planning-and-nepa/plans-in-development/alaska/BSWI.* On the project summary page, click on ''Documents'' on the left side of the screen to find the electronic version of this material. Hard copies of the Proposed RMP/Final EIS are also available for public inspection. Please contact each of the following facilities prior to visiting to determine the specific COVID–19 protocols in place, such as needing an appointment and face mask to enter:

BLM Anchorage Field Office, 4700 BLM Road, Anchorage, AK 99507, (907) 261–1246.

BLM Fairbanks District Office, 222 University Avenue, Fairbanks, AK 99709, (907) 474–2200.

BLM Alaska Public Information Center, James M. Fitzgerald Federal Building, 222 West 7th Avenue, Anchorage, AK 99513 (907) 271–5960.

Alaska Resources Library & Information Services, 3211 Providence Drive, Suite 111, Anchorage, AK 99508, (907) 272–7547.

All protests must be in writing and filed with the BLM Director, either as a hard copy or electronically via BLM's National NEPA Register by the close of the protest period. The only electronic protests the BLM will accept are those filed through BLM's National NEPA Register. All protest letters sent to the BLM via fax or email will be considered invalid unless a properly filed protest is also submitted.

Instructions for filing a protest may be found in the ''Dear Reader'' Letter of the Bering Sea–Western Interior Proposed RMP/Final EIS, at 43 CFR 1610.5–2, and online at *https://www.blm.gov/programs/ planning-and-nepa/public-participation/filing-a-plan-protest.* If you do not have the ability to file your protest electronically, hard copy protests must be mailed to one of the following addresses:

- *Regular Mail:* BLM Director (210), Attention: Protest Coordinator, P.O. Box 261117, Lakewood, CO 80226
- *Overnight Delivery:* BLM Director (210), Attention: Protest Coordinator, 2850 Youngfield Street, Lakewood, CO 80215.

Before including your phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

FOR FURTHER INFORMATION CONTACT: Jorjena Barringer, BLM Anchorage Field Office, telephone: (907) 267–1317,

email: *jbarringer@blm.gov.* People 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. 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 Bering Sea–Western Interior Planning Area is in western Alaska and encompasses approximately 62.3 million acres of land, including 13.5 million acres managed by the BLM.

This RMP replaces the 1981 Southwest Management Framework and a small portion of the 1986 Central Yukon Resource Management Plan, including amendments. It provides:

- Consolidated direction to address land and resource use and development on BLM-managed lands within the planning area under one RMP, and
- Analysis of the environmental effects that could result from the implementation of the alternatives proposed in the RMP/EIS.

The purpose of this Proposed RMP is to make decisions that guide future land management actions and site-specific implementation decisions. The decisions will address goals and objectives for resource management (desired outcomes) and establish land uses (allocations) that are allowable, restricted, or prohibited to achieve the goals and objectives. The need for this RMP is to provide guidance that will address the significant alterations in resources, circumstances, laws, policies, and regulations in the planning area since 1981.

The Proposed RMP/Final EIS evaluates five alternatives for managing the planning area. Alternative A, the no action alternative, represents existing management described by current land use plans and provides the benchmark against which to compare the other alternatives. Alternative B emphasizes reducing the potential for competition between recreational or developmental uses and subsistence resources by identifying key areas for additional management actions. Alternative C emphasizes adaptive management at the planning level to maintain the long-term sustainability of resources while providing for multiple resource uses. Alternative D provides additional flexibility at the site-specific implementation level and fewer management restrictions at the planning level. The Proposed RMP (Alternative E) emphasizes adaptive management at the planning level to protect the long-term sustainability of resources while providing for multiple resource uses. This alternative is meant to provide flexibility at the planning level while still providing enough direction to make processing of site-specific projects easier and more consistent. Alternatives B, C, D, and E were developed using input from the public, stakeholders, and cooperating agencies. Major planning issues addressed include subsistence resources, including water resources, fisheries, and wildlife; forestry; minerals and mining; recreation; travel management and access; and areas of critical environmental concern.

The BLM initiated the scoping process for the Bering Sea-Western Interior RMP with the publication of a Notice of Intent in the **Federal Register** on July 18, 2013 and concluded that scoping process 180 days later on January 17, 2014. The BLM requested agencies, tribes, groups, and the public to identify issues and concerns within the planning area. Scoping comments collected at public meetings and by emails, letters, and phone calls were used to identify issues and define the scope of analysis for management alternatives. Meetings were held in 10 communities with proximity to substantial blocks of BLM lands, the Iditarod National Historic Trail, the Unalakleet Wild River Corridor, and major watersheds in the planning area (Kuskokwim and Yukon Rivers). Local and regional news releases advertised the times and locations of these meetings. Additional detail on the public outreach efforts related to the scoping process is included in the Scoping Report (BLM 2014a).

During February and March of 2015, the BLM held public meetings in 14 communities that focused on explaining the preliminary alternatives for the future Draft RMP/EIS. The BLM released the Preliminary Alternatives Comment Summary Report in August 2015, which summarized input received on preliminary alternatives for the Draft RMP/EIS. The BLM used the comments, along with subsequently identified issues and planning criteria, to help formulate a reasonable range of alternatives for analysis in the Draft RMP/EIS.

The BLM provided additional public outreach when there were substantial project updates through its Bering Sea-Western Interior ePlanning website; mailing of postcards and flyers; seven newsletter publications; emailed eNews Blasts; and through press releases, newspaper advertisements, and radio public service announcements.

The 90-day public comment period on the Draft RMP/EIS ran from March 15, 2019, to June 13, 2019, with 17 public meetings held during that time to gather comments on the Draft RMP/EIS. The BLM engaged in a collaborative outreach and public involvement process during the public comment period that included federally recognized tribes, Alaska Native corporations, city, state, and federal agencies, non-governmental organizations, and the general public. The BLM collected comments on alternatives, objectives, and actions described in the Draft RMP/EIS. This Proposed RMP/Final EIS reflects changes and adjustments based on information received during public comment on the Draft RMP/EIS and new information. The Bering Sea-Western Interior Comment Summary Report (BLM 2019) provides additional detail on the public comment period, comments received, and how those comments were addressed in this Proposed RMP/Final EIS. A summary of comments received during the public comment period and responses to those comments is also included in Appendix G.

Authority: 16 U.S.C. 3120(a); 40 CFR 1506.6(b).

Chad B. Padgett,

State Director, Alaska.

[FR Doc. 2020–26646 Filed 12–3–20; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVL00000.L19900000.EX0000 21X MO #4500150160]

Notice of Availability of the Draft Environmental Impact Statement for the Robinson Mine Plan of Operations Amendment, White Pine County, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) Ely District (EYDO), Nevada, has prepared a Draft Environmental Impact Statement (EIS) for the Robinson Mine Plan of Operations Amendment project and by this notice is announcing its availability.

DATES: In order to have comments considered for inclusion in the Final EIS, the BLM must receive comments on

the Draft EIS by January 19, 2021, or 45 days following the date that the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**, whichever is greater. To maximize the opportunity for public input on this project while prioritizing the health and safety of BLM employees and the interested public, BLM will host online virtual public meetings to provide information and gather input on the project. The date(s) and information about how to login and participate in these virtual meetings will be announced at least 15 days in advance through local media and on the BLM website at *https://go.usa.gov/xvYad.* To ensure that comments will be considered, the BLM must receive written comments on the Draft EIS within 45 days following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**.

ADDRESSES: You may submit comments related to the Robinson Mine Plan of Operations Amendment Draft EIS by any of the following methods:

- Website: *https://go.usa.gov/xvYad*
- *Email: blm_nv_eydo_robinson_eis@blm.gov*
- Mail: BLM Ely District Office, ATTN: Project Manager, Tiera Arbogast, 702 North Industrial Way, Ely, Nevada 89301

Documents pertinent to this proposal may be examined at the Ely District Office.

FOR FURTHER INFORMATION CONTACT: Tiera Arbogast, telephone 775–289–1872, or email *tarbogast@blm.gov.* Contact Ms. Arbogast to have your name added to the mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Ms. Arbogast 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. Normal business hours are 7:30 a.m. to 4:30 p.m., Monday through Friday, except for Federal holidays.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM EYDO, Ely, Nevada, has published a Draft EIS for the Robinson Mine Plan of Operations Amendment project. The Robinson Mine is an 8,887.6 acre copper mining operation adjacent to Ruth, Nevada, seven miles west of Ely, Nevada via U.S. Route 50.

The KGHM Robinson Nevada Mining Company (KGHM Robinson) is proposing additional development at the Robinson Mine to extend mine life approximately 4 additional years beyond its currently anticipated permanent closure in 2024. To accomplish this, the company is proposing renewed mining in the eastern portions of its privately-owned Liberty Pit and a grant by the BLM to access and develop two specific areas of nearby BLM-managed public land on which to dispose newly generated waste rock.

Under the Proposed Action Alternative (Alternative B) the company would develop approximately 260 acres immediately south of the Robinson Mine to serve as the ''King'' waste rock storage facility. An alternative scenario would allow the company to develop approximately 102 acres of BLM lands and 67 acres of KGHM-owned land adjacent to its existing North Tripp waste rock facility. The company is also considering possible disposal of new waste rock within approximately 160 acres in its privately-owned Ruth East Pit, where no future mining is planned. Lastly, KGHM Robinson is seeking access to 94 private acres and approximately 545 acres of BLM lands adjacent to its existing Giroux Wash Tailings Storage Facility in order to (a) obtain soil material to use in increasing the height of the Giroux Wash main impoundment and the surrounding perimeter dams, and (b) to serve as growth media (*e.g.,* topsoil) storage areas to be used in future reclamation of areas of mining-related surface disturbance.

Under the No Action Alternative (Alternative A) the BLM would not approve the 2019 Robinson Mine Plan of Operations Amendment as written. Although KGHM Robinson could continue mining on their own private lands, no additional expansion onto BLM-managed public lands would be permitted. Without additional areas on which to dispose waste rock generated by continued mining, or the ability to obtain substantial additional volumes of soil to use in increasing the height of the primary impoundment and perimeter dams at the Giroux Wash Tailings Storage Facility (TSF), KGHM Robinson estimates that active operations at the Robinson Mine would cease in 2024.

The Reduced King Waste Rock Dump (WRD) and North Tripp WRD (Alternative C) would keep all project elements described in the 2019 Plan Amendment, including both the North Tripp and King WRDs; however, the allowable footprint of the King WRD would be reduced from the 260 acres under Alternative B to 234 acres under this alternative. Specifically, Alternative C would eliminate all proposed King WRD development east of County Road 44A. The North Tripp WRD would be expanded onto approximately 102 acres of BLM-managed public lands and 67 private acres. As with Alternative B, this alternative would include dewatering and renewed mining in the eastern portions of the Liberty Pit and development of approximately 545 acres of BLM-managed public land and 94 private acres adjacent to the Giroux Wash TSF. This alternative would result in approximately 869 acres of new disturbance on BLM-managed public lands and 237 acres of KGHM-owned private lands, for a total of approximately 1,106 acres of new surface disturbance. As with Alternative B, mine life would be extended to 2028,

The Ruth East Backfill and Reduced King WRD Alternative (Alternative D) is similar to Alternative B, the Proposed Action. Alternative D would include renewed dewatering and expanded mining operations in the eastern portions of the Liberty Pit as well as approval for KGHM Robinson to develop a total of approximately 639 acres of mixed public and private land adjacent to the Giroux Wash TSF. Alternative D, like Alternative C, would include the reduced 234-acre King WRD. Alternative D would, however, not include development of the North Tripp WRD. Rather, additional waste rock generated during continued mining would be disposed within approximately 160 acres of KGHM-owned lands within the Ruth East Pit. Approval of Alternative D would therefore result in approximately 767 acres of new surface disturbance on BLM-managed lands and 330 acres of KGHM-owned private lands, or a total of approximately 1,097 acres. As with Alternatives B and C, mine life would be extended to 2028.

The Notice of Intent for this project included the BLM's proposal to also amend the Ely District Resource Management Plan for Visual Resource Management classes. During scoping, however, the BLM determined that a Resource Management Plan amendment is not required, and therefore it is no longer being analyzed as part of this Draft EIS. On September 14, 2020, The Council on Environmental Quality's revision to the NEPA Regulations went into effect. The final rule does not apply to the NEPA analysis for the Robinson Mine Plan of Operations Amendment, as it began prior to September 14, 2020.

The purpose of the public review and comment process is to seek input on the range of alternatives and analysis of impacts presented in the Draft EIS. You may submit comments in writing to the BLM as shown in the **ADDRESSES** section above. To be considered, your

comments must be submitted by the close of the 45-day comment period.

The BLM has initiated ongoing consultation with Indian tribes on a government-to-government basis in accordance with Executive Order 13175 and other policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. The public is encouraged to comment on the range of alternatives and analysis presented in the Draft EIS.

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.

Authority: 40 CFR 1501.7 and 43 CFR 1610.2.

Jared Bybee,

Acting Field Manager, Bristlecone Field Office.

[FR Doc. 2020–26671 Filed 12–3–20; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031200; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Pueblo Grande Museum, City of Phoenix, AZ; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The Pueblo Grande Museum has corrected an inventory of human remains and associated funerary objects in a Notice of Inventory Completion published in the **Federal Register** on May 8, 2020. This notice corrects the minimum number of individuals and the number of associated funerary objects. 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 Pueblo Grande Museum. 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 Pueblo Grande Museum at the address in this notice by January 4, 2021.

ADDRESSES: Lindsey Vogel-Teeter, Pueblo Grande Museum, 4619 E. Washington Street, Phoenix, AZ 85034, telephone (602) 534–1572, email *lindsey.vogel-teeter@phoenix.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 correction of an inventory of human remains and associated funerary objects under the control of the Pueblo Grande Museum, Phoenix, AZ. The human remains and associated funerary objects were removed from Maricopa County, AZ, as well as unspecified locations within central or southern 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.

This notice corrects the minimum number of individuals and the number of associated funerary objects in a Notice of Inventory Completion published in the **Federal Register** (85 FR 27435–27443, May 8, 2020). Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (85 FR 27436, May 8, 2020), column 3, paragraph 3, is corrected by substituting the following paragraph:

Between 1936 and 1939, human remains representing, at minimum, 54 individuals were removed from site AZ U:9:1(ASM)/Pueblo Grande in Maricopa County, AZ, by PGM personnel. These excavations occurred in multiple areas of the site, and the majority of this work was conducted under the supervision of Julian Hayden. The human remains have been in the collections of PGM since they were excavated, but some individuals were not identified until 2018, during a review of the faunal and unprovenanced collections. The human remains belong to 37 cremated individuals and 17 individuals from inhumations. The individuals range in age from fetal to old adult and include both males and females. No known individuals were identified. The 125 associated funerary objects are 18 ceramic bowls of plain ware, red ware, and red-on-buff ware; eight ceramic jars of plain ware and Black Mesa black-on-white ware; one ceramic pitcher; one seed jar; three scoops of red ware and red-on-buff ware; four environmental samples; two lots of textile fragments; one spindle whorl; 13 lots of worked faunal bones that include awls; eight lots of shells; seven lots of shell jewelry that include bracelets, pendants, and beads; 25 lots of ceramic sherds of plain ware, red ware, red-on-buff ware, and polychrome ware; nine lots of faunal bones, including the remains of a red-tailed hawk burial; six vessel fragments/partial vessels; one piece of stone jewelry; one worked sherd; one polishing stone; one lot of charcoal; three lots of a white chalky substance (possibly burned caliche or shell); two axes; one hammerstone; one red-on-buff censer; three palettes; two lithics; one projectile point; one turtle carapace; and one figurine.

In the **Federal Register** (85 FR 274441, May 8, 2020), column 3, paragraph 6, sentence 1 is corrected by substituting the following sentence:

At an unknown time, human remains representing, at minimum, 21 individuals were removed from various unidentified locations in AZ.

In the **Federal Register** (85 FR 274441, May 8, 2020), column 3, paragraph 6, sentences 8–11 are corrected by substituting the following sentences:

Ten of the individuals are from inhumations and 11 of the individuals are from cremations. The individuals are of varying ages and sexes. No known individuals were identified. The four associated funerary objects are one lot ceramic sherds, one lot burned faunal bone, and two lots of burned shell.

In the **Federal Register** (85 FR 274442, May 8, 2020), column 3, paragraph 2, sentence 1, under the heading ''Determinations Made by the Pueblo Grande Museum,'' is corrected by substituting the following sentence:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 286 individuals of Native American ancestry.

In the **Federal Register** (85 FR 274442, May 8, 2020), column 3, paragraph 2, sentence 2, under the heading ''Determinations Made by the Pueblo Grande Museum,'' is corrected by substituting the following sentence:

- Pursuant to 25 U.S.C. 3001(3)(A), the 610 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.

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 Lindsey Vogel-Teeter, Pueblo Grande Museum, 4619 E. Washington Street, Phoenix, AZ 85034, telephone (602) 534–1572, email *lindsey.vogel-teeter@phoenix.gov,* by January 4, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the and the Ak-Chin Indian Community (previously listed as the 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; Tohono O'Odham Nation of Arizona; and the Zuni Tribe of the Zuni Reservation, New Mexico (hereafter referred to as ''The Tribes'') may proceed.

The Pueblo Grande Museum is responsible for notifying The Tribes that this notice has been published.

Dated: November 24, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–26761 Filed 12–3–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SERO–MEMY–NPS0030535; PPSESEROC3.PPMPSAS1Y.YP0000]

Medgar and Myrlie Evers Home National Monument

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: As authorized by the John D. Dingell, Jr. Conservation, Management, and Recreation Act, the National Park Service announces that the Secretary of the Interior (Secretary) has established, in the State of Mississippi, Medgar and Myrlie Evers Home National Monument (National Monument) as a unit of the National Park System. This National Monument is established to preserve, protect, and interpret for the benefit of present and future generations resources associated with the pivotal roles of Medgar and Myrlie Evers in the American Civil Rights Movement.

FOR FURTHER INFORMATION CONTACT: Lance Hatten, Deputy Regional Director, National Park Service, South Atlantic Gulf Regional Office at (404) 507–5605.

SUPPLEMENTARY INFORMATION: Section 2301 of the John D. Dingell, Jr. Conservation, Management, and Recreation Act, Public Law 116–9 includes a specific provision relating to establishment of this unit of the National Park System. To establish the National Monument, the Secretary must determine that a sufficient quantity of land, or interests in land, has been acquired to constitute a manageable park unit. The National Park Service typically publishes notice of the establishment of the new System unit in the **Federal Register** no later than 30 days after the Secretary makes a determination of this sort.

Medgar Evers was the first Mississippi field secretary for the National Association for the Advancement of Colored People (NAACP) and was at the forefront of every major civil rights event in Mississippi from 1955 until his assassination in 1963. While Medgar was the public face of the NAACP in Mississippi, Myrlie Evers worked behind the scenes running the NAACP field office in Jackson, drafting speeches, and providing personal and logistical support for her husband and other civil rights workers. After her husband's death, Myrlie assumed a public role in the civil rights movement. Soon after his funeral, she began speaking at NAACP events across the nation, eventually becoming the first woman to chair the board of the NAACP from 1995 to 1998.

The assassination of Medgar Evers on June 12, 1963, in the carport of the couple's home was the first murder of a civil rights leader that focused national attention on the civil rights movement. His death heightened public awareness throughout the United States of civil rights issues and became one of the catalysts for the passage of the Civil Rights Act of 1964. The National Park Service acquired by general warranty deed the fee simple interests in the approximately 0.15-acre parcel of land that includes the family home on June 18, 2020.

On November 9, 2020, the Secretary of the Interior signed a Decision Memorandum determining that a sufficient quantity of land, or interests in land, had been acquired to constitute a manageable park unit. With the signing of this Decision Memorandum by the Secretary, the site to be known as the ''Medgar and Myrlie Evers Home National Monument'' was established as a unit of the National Park System, effective November 9, 2020, and is subject to all laws, regulations, and policies pertaining to such units.

Margaret Everson,

Counselor to the Secretary, Exercising the Delegated Authority of the Director.

[FR Doc. 2020–26693 Filed 12–3–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031202; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Robert S. Peabody Institute of Archaeology, Andover, MA; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The Robert S. Peabody Institute of Archaeology (formerly the Robert S. Peabody Museum of Archaeology) has corrected an inventory of human remains and associated funerary objects, published in a Notice of Inventory Completion in the **Federal Register** on August 5, 2019. This notice corrects the number of individuals and associated funerary objects. 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 associated funerary objects should submit a written request to the Robert S. Peabody Institute of Archaeology. If no additional requestors come forward, transfer of control of the 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 Robert S. Peabody Institute of Archaeology at the address in this notice by January 4, 2021.

ADDRESSES: Ryan Wheeler, Robert S. Peabody Institute of Archaeology, 180 Main Street, Andover MA 01810, telephone (978) 749–4490, email *rwheeler@andover.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 correction of an inventory of human remains and associated

funerary objects under the control of the Robert S. Peabody Institute of Archaeology, Andover, MA. The human remains and associated funerary objects were removed from four sites in FL.

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.

This notice corrects the number of individuals and associated funerary objects published in a Notice of Inventory Completion in the **Federal Register** (84 FR 38045–38047, August 5, 2019). During preparation for repatriation, one additional set of human remains and additional associated funerary objects from Macey Mound, FL, were identified. These human remains and associated funerary objects were removed by Fred Alanson Luce and his son Stanley Eldridge Luce around 1940. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (84 FR 38045, August 5, 2019), column 3, paragraph 4, sentence 1, under the heading ''History and Description of the Remains,'' is corrected by substituting the following sentence:

In January 1920, human remains representing, at minimum, ten individuals were removed by Fred Alanson Luce and his son Stanley Eldridge Luce from the Macey Mound (8OR10313) in Orange County, FL.

In the **Federal Register** (84 FR 38045, August 5, 2019), column 3, paragraph 4, sentence 6 is corrected by substituting the following sentence:

Examination by physical anthropologists Michael Gibbon and Harley Erickson, and Peabody staff members found that the human remains represent two adults of indeterminate sex; four adult males; one adult, possibly female; two juveniles of indeterminate sex; and one cremated individual.

In the **Federal Register** (84 FR 38045, August 5, 2019), column 3, paragraph 4, sentence 8 is corrected by substituting the following sentence:

The 1,727 associated funerary objects are one charcoal sample; one whelk shell columella; one shell bead; one stone plummet; nine quartz pebbles; three chert bifaces; one sand sample; and 1,710 pottery sherds.

In the **Federal Register** (84 FR 38046, August 5, 2019), column 3, paragraph 2, sentence 1, under the heading ''Determinations Made by the Robert S. Peabody Institute of Archaeology,'' is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 13 individuals of Native American ancestry.

In the **Federal Register** (84 FR 38046, August 5, 2019), column 3, paragraph 2, sentence 2 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(3)(A), the 1,737 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.

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 Ryan Wheeler, Robert S. Peabody Institute of Archaeology, 180 Main Street, Andover, MA 01810, telephone (978) 749–4490, email *rwheeler@andover.edu,* by January 4, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Miccosukee Tribe of Indians; Seminole Tribe of Florida (previously listed as the Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations)); and The Seminole Nation of Oklahoma may proceed.

The Robert S. Peabody Institute of Archaeology is responsible for notifying The Consulted and Invited Tribes identified in the August 5, 2019 notice that this notice has been published.

Dated: November 24, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–26759 Filed 12–3–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031208; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Department of the Navy, Navy Region Southeast, Jacksonville, FL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of the Navy, Navy Region Southeast, has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. 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 should submit a written request to the Department of the Navy, Navy Region Southeast. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: 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 should submit a written request with information in support of the request to the Department of the Navy, Navy Region Southeast, at the address in this notice by January 4, 2021.

ADDRESSES: Dr. John Calabrese, Navy Region Southeast, Naval Air Station Jacksonville, Building 135N, Jacksonville, FL 32212, telephone (904) 542–6985, email *john.calabrese@navy.mil.*

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 under the control of the United States Navy, Navy Region Southeast, Jacksonville, FL. The human remains were removed from Naval Submarine Base Kings Bay, Camden County, GA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). 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. 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 the Navy, Navy Region Southeast professional staff in consultation with representatives of the Cherokee Nation; Eastern Band of Cherokee Indians; Miccosukee Tribe of Indians; Poarch

Band of Creeks (previously listed as Poarch Band of Creek Indians of Alabama); Seminole Tribe of Florida (previously listed as Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations)); The Chickasaw Nation; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; Thlopthlocco Tribal Town; and the United Keetoowah Band of Cherokee Indians in Oklahoma (hereafter referred to as ''The Consulted Tribes'').

History and Description of the Remains

Between 1979 and 1986, human remains representing, at minimum, 10 individuals were removed from the following seven sites in Camden County, GA: Kings Bay Site (9CM171); Kings Bay Site (9CM171B); Kings Bay Site, Poisonberry Area (9CM171A); Devils Walking Stick, South Bunker Area (9CM177B); Kings Bay Planation Site, Area 1 (9CM172); Kings Bay Planation Site, South Trunk Line Area (9CM172); and Kings Bay Site, Wharf Area (9CM171J). All archeological materials from these investigations, including the human remains, were initially curated at the University of Florida, Florida Museum of Natural History, in Gainesville, FL. In May 2000, they were transferred to the United States Army Corps of Engineers, Mandatory Center of Expertise for the Curation and Management of Archaeological Collections in St. Louis, MO. In September 2002, the human remains were transferred to Naval Submarine Base Kings Bay, and the other materials were sent to the University of Georgia, Athens Laboratory of Archaeology for permanent curation. In March 2017, the human remains were transferred to Navy Region Southeast in Jacksonville, FL.

Kings Bay Site (9CM171)

In 1979, human remains representing, at minimum, one individual, were recovered under the direction of the Department of Anthropology, University of Florida through a contract with the United States Navy. The human remains belong to an adult of undetermined sex. No known individual was identified. No associated funerary objects are present. The human remains were removed from trenched spoil. Late Archaic (3,000 to 1,000 B.C.) St. Simons fiber-tempered ceramics and Swift Creek Complicated Stamp pottery (A.D. 300 to 900) were recovered from the site.

Kings Bay Site (9CM171B)

Between November 1979 and February 1980, human remains representing, at minimum, one individual, were excavated under the direction of the Department of Anthropology, University of Florida through a contract with the United States Navy. The human remains belong to a female. No known individual was identified. No associated funerary objects are present. The human remains were removed from an articulated burial. A single radiocarbon assay from the surrounding soil dates between A.D. 625 and 1020, and the fragmentary ceramic assemblage from the surrounding soil indicates a generalized St. Johns period component.

Kings Bay Site, Poisonberry Area (9CM171A)

In 1981, human remains representing, at minimum, one individual, were excavated under the direction of the Department of Anthropology, University of Florida through a contract with the United States Navy. The human remains comprise two tooth fragments (an incisor crown and a molar crown). No known individual was identified. No associated funerary objects are present. The human remains were found in a shell midden with a predominantly Swift Creek (Late Woodland, A.D. 300 to 900) component.

Devils Walking Stick, South Bunker Area (9CM177B)

In 1981, human remains representing, at minimum, one individual, were excavated under the direction of the Department of Anthropology, University of Florida through a contract with the United States Navy. The human remains comprise a single tooth crown. No known individual was identified. No associated funerary objects are present. The human remains were recovered from a midden deposit. While the excavation records are too imprecise to place the human remains in a specific prehistoric component, the site itself dates to the Savannah (A.D. 900–1550) and Protohistoric (A.D. 1550+) Periods.

Kings Bay Planation Site, Area 1 (9CM172)

In 1984, human remains representing, at minimum, three individuals were recovered by a professional archeologist under contract to the United States Navy. The human remains belong to two adults and one adolescent. No known individuals were identified. No associated funerary objects are present. The human remains were removed from the ground surface of a highly disturbed former shell midden during archeological monitoring for a building foundation and a utility trench. The midden contained a combination of Woodland (Deptford and Swift Creek, 800 B.C.–A.D. 900) and Mississippian (Savannah and Irene/San Marcos, A.D. 900–1540) components.

Kings Bay Planation Site, South Trunk Line Area (9CM172)

In 1984, human remains representing, at minimum, two individuals were recovered by a professional archeologist under contract to the United States Navy. The human remains belong to two adult males. No known individuals were identified. No associated funerary objects are present. The human remains were removed from measured test unit excavations undertaken after suspected human remains were inadvertently discovered during a waterline trench excavation. While no cultural components were directly associated with the human remains, the site itself produced both Woodland (Weeden Island Deptford, Weeden Island and Swift Creek, 800 B.C.–A.D. 900) and Mississippian (Savannah, A.D. 900 to 1350) components.

Kings Bay Site, Wharf Area (9CM171J)

In 1986, human remains representing, at minimum, one individual were excavated by a professional archeologist under contract to the United States Navy, Naval Submarine Base Kings Bay. The incomplete skeletal remains belong to an adult of undetermined sex. No known individual was identified. No associated funerary objects are present. The human remains were recovered from a shell midden during the expansion of the wharf. When found, the human remains were in a flexed position, and in conjunction with a single diagnostic ceramic fragment from the larger Weeden Island Period (A.D. 300 to 900).

Determinations Made by the Department of the Navy, Navy Region Southeast

Officials of the Department of the Navy, Navy Region Southeast have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on their recovery from prehistoric archeological sites.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 10 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.

• At the time of the early colonial period, the area encompassing Naval Submarine Base Kings Bay was occupied by the Timucua, a Muskogean (or, alternatively, a Siouan or Arawakan-speaking) group (Milanich 2004). After 1595, with the expansion of the Spanish mission system in La Florida, the Timucua became actively subject to the Spanish Crown. By the early 18th century a combination of disease, forced relocation by the Spanish, and enslavement had reduced the Timucua population to a few hundred. The reduction of Timucua numbers between the 16th and 18th centuries allowed for the expansion of other Muskogean peoples into the region. The terms of the Treaty of Augusta, signed in 1763 (a corollary to the Treaty of Paris ending the Seven Years War), ceded the Georgia coast, including what is currently St. Marys, GA, from the Creek Indians to the British Crown. Subsequently, the Treaty of 1790 and the Treaty of Colerain (1796) ceded additional lands by the Creek in Georgia and elsewhere to the United States. Consequently, the land from which the Native American human remains were removed is the aboriginal land of Creek peoples, including the Miccosukee Tribe of Indians; Poarch Band of Creeks (previously listed as Poarch Band of Creek Indians of Alabama); Seminole Tribe of Florida (previously listed as Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations)); The Chickasaw Nation; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; and the Thlopthlocco Tribal Town (hereafter referred to as ''The Tribes'').

• Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

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 should submit a written request with information in support of the request to Dr. John Calabrese, United States Navy, Navy Region Southeast, Naval Air Station Jacksonville, Jacksonville, FL 32212, telephone (904) 542–6985, email *john.calabrese@navy.mil,* by January 4, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Department of the Navy, Navy Region Southeast is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: November 24, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–26758 Filed 12–3–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PPMWSTGE00.PPMPSPD1Z.YM0000]

Ste. Genevieve National Historical Park

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: As authorized by the Consolidated Appropriations Act of 2018, the National Park Service announces that the Secretary of the Interior has established, in the State of Missouri, Ste. Genevieve National Historical Park, as a unit of the National Park System.

FOR FURTHER INFORMATION CONTACT: Tokey Boswell, Midwest Regional Office, at (402) 661–1534.

SUPPLEMENTARY INFORMATION: Section 101 of the Consolidated Appropriations Act of 2018 incorporated by reference Section 7134 of S.1460 Energy and Natural Resources Act of 2017. This act includes specific provisions relating to establishment of Ste. Genevieve National Historical Park as a unit of the National Park System. To establish the historical park, the Secretary must determine that sufficient land has been acquired to constitute a manageable park unit; and enter into a written agreement providing that land owned by the State, the City of Ste. Genevieve, or other entity within the Historic District shall be managed consistent with the purposes of the establishing legislation.

The Federal Government now owns, in fee simple title, two historic buildings and their associated property. The first property was donated by the State of Missouri on March 14, 2019. On January 30, 2020, the Society of Colonial Dames in America, Missouri Chapter donated the Jean Baptiste-Valle home to add to the site. In July of 2020, the State of Missouri signed transfer agreements for multiple parcels of land and two buildings within the boundary of the park that total an additional 10.54 acres. The National Park Service is currently performing the due diligence to acquire these properties. There are also four other individual properties totaling approximately 1.09 acres with signed letters of intent to sell or donate. In total, these parcels constitute sufficient lands to constitute a manageable unit of the National Park System.

The Secretary, through the National Park Service, has also entered into written agreements on August 31, 2018, with the City of Ste. Genevieve, the State of Missouri Department of Natural Resources, Ste. Genevieve County, the Foundation for the Restoration of Ste. Genevieve, the Society of Colonial Dames in America, Missouri Chapter, and Chaumette, Inc., providing that land and properties owned by those entities shall be managed consistent with the purposes of the establishing legislation.

On August 26, 2020, the National Park Service entered into a second agreement with the City of Ste. Genevieve to operate out of the City's existing welcome center.

On October 30, 2020, the Secretary of the Interior signed a Decision Memorandum determining that sufficient lands and agreements have been acquired to constitute a manageable park unit. With the signing of this Decision Memorandum by the Secretary, the site to be known as the ''Ste. Genevieve National Historical Park'' was established as a unit of the National Park System, effective October 30, 2020, and is subject to all laws, regulations, and policies pertaining to such units.

Margaret Everson,

Counselor to the Secretary, Exercising the Delegated Authority of the Director, National Park Service.

[FR Doc. 2020–26694 Filed 12–3–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031201; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: The University of California Berkeley, Berkeley, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The University of California Berkeley 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 University of California Berkeley. 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 University of California Berkeley at the address in this notice by January 4, 2021.

ADDRESSES: Dr. Thomas Torma, NAGPRA Liaison, Office of the Vice Chancellor for Research, University of California Berkeley, 119 California Hall, Berkeley, CA 94720–1500, telephone (512) 672–5388, email *t.torma@berkeley.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 University of California Berkeley, Berkeley, CA. The human remains and associated funerary objects were removed from around Humboldt Bay, Humboldt County, CA.

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 University of California Berkeley professional staff in consultation with representatives of the Wiyot Tribe, California (previously listed as Table Bluff Reservation—Wiyot Tribe).

History and Description of the Remains

In the early 20th century, human remains representing, at minimum, 14 individuals were removed from sites CA–HUM–68, CA–HUM–33, CA–HUM–23, and CA–HUM–112 in Humboldt County, CA. These human remains were collected by H.H. Stuart, an amateur archeologist based in Eureka, CA, and were part of a donation that was accessioned into the museum in 1931. Most of the individuals are represented by a very small number of bones, and because the digs were not well documented, the age and the sex of the individuals were not recorded. No known individuals were identified. The one associated funerary object is one set of unidentified animal bones.

Between July and October 1913, human remains representing, at minimum, seven individuals were removed from sites CA–HUM–33, and CA–HUM–37, near the Mad River Slough, in Humboldt County, CA. These human remains were collected by Llewellyn Loud, who was working on an ethnogeographic and archeological survey of the Wiyot people under the direction of Alfred Kroeber. The human remains were accessioned on November 6, 1913. No associated funerary objects are present.

Most of the sites around Humboldt Bay date to the creation of the Bay, approximately 5000–7000 years ago. According to archeological evidence, Wiyot oral tradition, and the written historical record, the Wiyot Tribe has been present in this area since before the creation of Humboldt Bay.

Determinations Made by the University of California Berkeley

Officials of the University of California Berkeley have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 21 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the one object 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 Wiyot Tribe, California (previously listed as Table Bluff Reservation—Wiyot Tribe).

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 Dr. Thomas Torma, NAGPRA Liaison, Office of the Vice Chancellor for Research, University of California Berkeley, 119 California Hall, Berkeley, CA 94720–1500, telephone (512) 672–5388, email *t.torma@berkeley.edu,* by January 4, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Wiyot Tribe, California (previously listed as Table Bluff Reservation—Wiyot Tribe) may proceed.

The University of California Berkeley is responsible for notifying the Wiyot Tribe, California (previously listed as Table Bluff Reservation—Wiyot Tribe) that this notice has been published.

Dated: November 24, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–26760 Filed 12–3–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031199; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Cleveland Museum of Natural History, Cleveland, OH

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Cleveland Museum of Natural History (CMNH), in consultation with the appropriate Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definitions of unassociated funerary objects and sacred objects and has determined that there is a cultural affiliation between the objects and a present-day Native Hawaiian organization. Lineal descendants or representatives of any Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the CMNH. If no additional claimants come forward, transfer of control of the cultural items to the Native Hawaiian organization stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Native Hawaiian organization not identified in this notice that wish to submit a claim for these cultural items should submit a written request with information in support of the claim to the CMNH at the address in this notice by January 4, 2021.

ADDRESSES: Dr. Brian Redmond, Cleveland Museum of Natural History, 1

Wade Oval Drive, Cleveland, OH 44106, telephone (216) 231–4600 Ext. 3301, email *bredmond@cmnh.org* or Amanda McGee, telephone (216) 231–4600 Ext. 3275, email *amcgee@cmnh.org.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Cleveland Museum of Natural History, Cleveland, OH, that meet the definition of unassociated funerary objects and sacred objects under 25 U.S.C. 3001.

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 cultural items. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the cultural items was made by CMNH staff in consultation with representatives of the Office of Hawaiian Affairs (OHA).

History and Description of the Cultural Items

In 1935, six Hawaiian burial tapa cloths were removed from ancient Native Hawaiian corpses in burial caves on Hawai'i Island by Glenn W. Russ of the Bernice Pauahi Bishop Museum (BPBM). The exact location of the burial caves is unknown. At some time soon after the collection of the burial cloths, Russ transferred them to D' Alte Welch, who also worked at BPBM. In 1976, Welch, who became a professor at John Carroll University in Ohio, donated the burial tapas to CMNH. The accession numbers for these six items are #1976–03: CMNH #s 8460, 8464, 8470, 8476, 8480, 8482. Welch also donated to CMNH one 22-page scrapbook (CMNH #8458) containing burial tapa fragments.

In the early 20th century, one cultural item, a ''Hawaiian necklace'' (lei niho palaoa) made of human hair, was acquired by Mrs. H.F. Lyman. It is unknown from where in Hawaii the lei niho palaoa had been removed or the circumstances of its removal. In 1922, Mrs. Lyman donated the lei niho palaoa to CMNH (accession #7, CMNH# 1682). CMNH has determined that the lei niho palaoa is authentic and is used in traditional Native Hawaiian religious ceremonies.

Determinations Made by the Cleveland Museum of Natural History

The Cleveland Museum of Natural History have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the one 22-page scrapbook of burial tapa fragments and the six burial tapa cloths described above 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 and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of Native Hawaiian individuals.
- Pursuant to 25 U.S.C. 3001(3)(C), the one lei niho palaoa described above is a specific ceremonial object needed by traditional Native Hawaiian religious leaders for the practice of traditional Native Hawaiian religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the cultural objects and the Office of Hawaiian Affairs.

Additional Requestors and Disposition

Lineal descendants or representatives of any Native Hawaiian organization not identified in this notice that wish to submit a claim for these cultural items should submit a written request with information in support of the claim to Dr. Brian Redmond, Cleveland Museum of Natural History, 1 Wade Oval Drive, Cleveland, OH 44106, telephone (216) 231–4600 Ext. 3301, email *bredmond@cmnh.org* or Amanda McGee, telephone (216) 231–4600 Ext. 3275, email *amcgee@cmnh.org,* by January 4, 2021. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects and the sacred object to the Office of Hawaiian Affairs listed in this notice may proceed.

The Cleveland Museum of Natural History is responsible for notifying the Office of Hawaiian Affairs that this notice has been published.

Dated: November 24, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–26762 Filed 12–3–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Gulf of Mexico, Outer Continental Shelf, Geological and Geophysical Activities: Western, Central, and Eastern Planning Areas; Final Programmatic Environmental Impact Statement

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of availability of a record of decision.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) is announcing the availability of a Record of Decision for the final programmatic environmental impact statement (EIS) for proposed geological and geophysical (G&G) activities on the Gulf of Mexico (GOM) Outer Continental Shelf (OCS). This Record of Decision identifies BOEM's selected alternative for conducting proposed G&G activities on the Gulf of Mexico OCS, which is analyzed in the *Gulf of Mexico OCS Proposed Geological and Geophysical Activities: Western, Central, and Eastern Planning Areas; Final Programmatic Environmental Impact Statement* (Programmatic EIS). The Record of Decision and associated information are available on BOEM's website at *http://www.boem.gov//or https://www.boem.gov/regions/gulf-mexico-ocs-region/resource-evaluation/gulf-mexico-geological-and-geophysical-gg.*

FOR FURTHER INFORMATION CONTACT: For more information on the Record of Decision, you may contact Ms. Helen Rucker, Chief, Environmental Assessment Section, Office of Environment, by telephone at 504–736–2421 or by email at *helen.rucker@boem.gov.*

SUPPLEMENTARY INFORMATION: The Programmatic EIS addresses potential environmental impacts of BOEM's Oil and Gas, Renewable Energy, and Marine Minerals Programs, and focuses particularly on the environmental impacts of off-lease and on-lease geological (bottom sampling and test drilling) and geophysical (deep-penetration, high—resolution geophysical (HRG), electromagnetic, deep stratigraphic, and remote sensing) surveys. The area evaluated (*i.e.,* Area of Interest or AOI) includes the OCS waters that are within BOEM's Gulf of Mexico planning areas (*i.e.,* Western, Central, and Eastern Planning Areas). The AOI also includes, for purposes of the analysis, the coastal waters of Texas, Louisiana, Mississippi, Alabama, and Florida extending from the coastline

outside of estuaries seaward 3 nautical miles (nmi) (3.5 miles [mi]; 5.6 kilometers [km]) from Louisiana, Mississippi, and Alabama, or 9 nmi (10.4 mi; 16.7 km) from Texas and Florida to the limit of State jurisdiction.

In the Programmatic EIS, BOEM evaluated seven alternatives. All but the No Action Alternative focused on mitigation measures to avoid or reduce the potential environmental impacts that could result from future G&G activities in the GOM. The Programmatic EIS and Record of Decision are available at *https://www.boem.gov/regions/gulf-mexico-ocs-region/resource-evaluation/gulf-mexico-geological-and-geophysical-gg.*

After careful consideration, the Record of Decision identifies BOEM's selection of Alternative C of the Programmatic EIS. Under Alternative C, G&G activities would continue to be permitted and authorized, and would include the mitigation measures, monitoring, reporting, survey protocols, and guidance that were in place prior to the settlement agreement in *Natural Resources Defense Council Ins., et al.,* v. *Bernhardt, et al., Defendants and API, et al., Intervenor, Defendants, No. 2:10–cv–01882 (E.D. La.),* as well as additional mitigation and temporal measures for survey protocols for seismic airgun and nonairgun HRG surveys. While BOEM is selecting Alternative C at this programmatic stage, rather than adopting the non-airgun, HRG survey protocol (as described in Appendix B of the Programmatic EIS), the protocol will be reserved, considered, and applied at the site-specific stage, on an as-needed basis, to further minimize the potential for injury to marine mammals and sea turtles. BOEM's selection of the Preferred Alternative meets the purpose of and need for the proposed action, balances regional and national policy considerations, and includes appropriate measures to minimize potential environmental and socioeconomic impacts. This decision does not by itself authorize any activities. The mitigation measures contemplated in Alternative C may be supplemented by additional requirements or tailored as site-specific circumstances warrant in permits or other specific authorizations after BOEM completes additional environmental review.

Authority: This Notice of Availability of a Record of Decision is published pursuant to the regulations (40 CFR part 1503; 1978, as amended in 1986 and 2005) implementing the provisions of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Michael A. Celata,

Regional Director, New Orleans Office.

[FR Doc. 2020–26781 Filed 12–3–20; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1220]

Certain Filament Light-Emitting Diodes and Products Containing Same (II); Notice of Commission Decision Not To Review an Initial Determination Granting a Motion to Intervene

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 14) of the presiding administrative law judge (''ALJ'') granting a motion to intervene filed by non-party Signify North America Corp. (''Signify'').

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On October 5, 2020, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by The Regents of the University of California (''Complainant''). *See* 85 FR 62761–62 (Oct. 5, 2020). The complaint, as supplemented, alleges a violation of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain filament light-emitting diodes and products containing the same by reason of infringement of certain claims of U.S. Patent Nos. 9,240,529; 9,859,464; 10,593,854; 10,644,213; and 10,658,557. *See id.* The notice of investigation names the following respondents: General Electric Company of Boston, Massachusetts; Consumer Lighting (U.S.) LLC, d/b/a GE Lighting of Cleveland, Ohio; Savant Systems, Inc. of Hyannis, Massachusetts; Home Depot Product Authority, LLC; Home Depot U.S.A., Inc.; and The Home Depot, Inc. of Atlanta, Georgia; Feit Electric Company, Inc. of Pico Rivera, California; Satco Products, Inc. of Brentwood, New York; IKEA Supply AG of Pratteln, Switzerland; IKEA U.S. Retail LLC of Conshohocken, Pennsylvania; and IKEA of Sweden AB of Almhult, Sweden. *See id.* The Office of Unfair Import Investigations (''OUII'') is also a party to the investigation. *See id.*

On October 26, 2020, Signify filed a motion to intervene in this investigation pursuant to Commission Rule 210.19 (19 CFR 210.19). Signify argued that its motion is timely and that ''[i]ntervention is necessary so that Signify may properly defend its LED products that are alleged to be imported and/or sold after importation by the Home Depot Respondents.'' *See* Mot. at 1. No party opposed the motion to intervene except that Complainant argued that Signify should not be allowed to intervene as to the issue of domestic industry because Signify's interests on that issue are adequately represented by the existing parties. *See* Complainant's Resp. at 3 (Nov. 2, 2020). On November 2, 2020, OUII filed a response in support of the motion to intervene.

On November 5, 2020, the ALJ issued the subject ID (Order No. 14) granting Signify's motion to intervene. The ID notes that ''[n]o party disputes that Signify should be allowed to intervene.'' *See* ID at 2. The ID finds that ''Signify may fully participate as a party in the investigation, including with respect to all claims and defenses at issue in the investigation.'' *See id.* No petition for review of the subject ID was filed.

The Commission has determined not to review the subject ID. Signify is an intervenor in this investigation.

The Commission's vote for this determination took place on November 30, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 30, 2020.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2020–26660 Filed 12–3–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–1233]

Certain Active Optical Cables and Products Containing the Same; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on October 29, 2020, under section 337 of the Tariff Act of 1930, as amended, on behalf of Cosemi Technologies, Inc. of Irvine, California. A supplement to the complaint was filed on November 16, 2020. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain active optical cables and products containing the same by reason of infringement of certain claims of U.S. Patent No. 8,948,197 (''the '197 patent''), U.S. Patent No. 9,641,250 (''the '250 patent''), U.S. Patent No. 9,971,115 (''the '115 patent''), and U.S. Patent No. 9,979,479 (''the '479 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained 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 at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Katherine Hiner, Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2020).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 30, 2020, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1, 5, 6, 13–15, and 19 of the '197 patent; claims 1–5, 8–10, and 13 of the '250 patent; claims 1–6, 9, and 12–16 of the '115 patent, and claims 15, 18, and 25 of the '479 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''active optical data cables, including USB cables (USB A, A/C, C/C [USB and Display Port alt-mode variations], and A/micro-B [hybrid]), HDMI cables, and Display Port cables and products incorporating the same'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Cosemi Technologies, Inc., 1370 Reynolds Avenue, Suite 100, Irvine, CA 92614

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

EverPro Technologies Company Ltd., #9 Guanggu Road, Wuhan, Hubei 430073, China

Fibbr Technologies, #9 Optics Valley Avenue, East Lake Hi-tech Development Zone, Wuhan, Hubei 430073, China

Logitech Inc., 7700 Gateway Blvd., Newark, CA 94560

Facebook Technologies, LLC, 1 Hacker Way, Menlo Park, CA 94025

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not be named as a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 30, 2020.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2020–26682 Filed 12–3–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1158]

Certain Digital Video Receivers, Broadband Gateways, and Related Hardware and Software Components; Notice of a Commission Determination to Grant a Joint Motion To Terminate the Investigation in Its Entirety Based on a Settlement Agreement; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to grant a joint motion terminating the investigation as to Comcast Corporation, Comcast Cable Communications, LLC, Comcast Cable Communications Management, LLC, and Comcast Holdings Corporation (collectively, ''Comcast''), all of Philadelphia, Pennsylvania, based on a settlement agreement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Clint Gerdine, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone 202–205–1810.

SUPPLEMENTARY INFORMATION: On May 29, 2019, the Commission instituted this investigation based on a complaint filed by Rovi Corporation and Rovi Guides, Inc. (collectively, ''Rovi''), both of San Jose, California. 84 FR 24814–15 (May 29, 2019). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital video receivers, broadband gateways, and related hardware and software components by reason of infringement of certain claims of U.S. Patent Nos. 7,779,445 (''the '445 patent''); 7,200,855 (''the '855 patent''); 8,156,528 (''the '528 patent''); 8,001,564 (''the '564 patent''); 7,301,900 (''the '900 patent''); and 7,386,871 (''the '871 patent''). The complaint further alleged the existence of a domestic industry. The Commission's notice of investigation named Comcast as respondents. The Office of Unfair Import Investigations (''OUII'') is partially participating in the investigation. The '528, '855, and '445 patents remain in the investigation and the '564, '900, and '871 patents have been terminated from the investigation. Order No. 18 (Sept. 30, 2019), *unreviewed by* Comm'n Notice (Oct. 15, 2019).

On July 14, 2020, the ALJ issued a written *Markman* Order. *See* Order No. 41 (Jul. 14, 2020).

On July 28, 2020, the ALJ issued the final ID finding a violation of section 337 as to the '528 and '855 patents based on infringement of the asserted claims by Comcast's accused products. Specifically, the ID found that: (1) Comcast's accused products infringe claims 13, 27, and 30 of the '528 patent and claims 60 and 63 of the '855 patent; (2) Comcast's accused products do not infringe asserted claim 5 of the '445 patent; (3) the asserted claims of the '528 and '855 patents are not invalid; (4) claims 5 and 15 of the '445 patent are invalid as anticipated under 35 U.S.C. 102(g)(2) by Comcast's VOD Vision System; and (5) Rovi has satisfied both prongs of the domestic industry requirement. The ALJ's recommended determination recommended the issuance of a limited exclusion order directed to Comcast's infringing products and cease and desist orders directed to Comcast.

On August 10, 2020, Rovi petitioned, and Comcast petitioned and contingently petitioned, for review of the final ID. On August 18, 2020, Rovi and Comcast each filed a response in opposition to the other party's petition for review.

On October 9, 2020, the Commission determined to review the final ID in part. Specifically, the Commission determined to review: (1) Order No. 41's and the ID's construction of the claim limitations: ''same functions,'' ''personal video recorder device,'' ''personal video recorder-compliant device,'' ''personal video recorder functionality,'' and ''first interactive television program guide . . . are implemented'' (''where the first interactive television program guide and the second interactive program guide . . . are distinctly implemented'') of asserted claims 13, 27, and 30 of the '528 patent; (2) the ID's finding that Comcast's Accused Products infringe the asserted claims of the '528 patent and that the asserted claims are not invalid; (3) the ID's finding that Rovi has satisfied the technical prong of the domestic industry requirement with respect to the '528 patent; (4) the ID's identification of Comcast's products that infringe the asserted claims of the '855 patent; (5) the ID's finding that Comcast's redesigns for the '855 patent are not sufficiently fixed in design to warrant adjudication; (6) the ID's finding that the Accused Products are not ''articles that infringe'' claim 5 of the '445 patent; (7) the ID's finding that claims 5 and 15 of the '445 patent are invalid as anticipated under 35 U.S.C. 102(g)(2) by Comcast's VOD Vision System; (8) the ID's finding that Comcast has engaged in sales within the United States after importation of accused products in accordance with section 337(a)(1)(B); and (9) the ID's finding that Rovi satisfied the economic prong of the domestic industry requirement. 85 FR 66357–58 (Oct. 19, 2020). The Commission determined not to review the remainder of the final ID. *Id.* The Commission also requested the parties to respond to certain questions concerning the issues under review with respect to Order No. 41 and the final ID, and requested written submissions on the issues of remedy, the public interest, and bonding from the parties and interested non-parties. *Id.*

On October 23 and 30, 2020, Rovi and Comcast each filed a brief and a reply brief, respectively, on all issues for which the Commission requested written submissions. On the same dates, OUII filed a brief and a reply brief on remedy, the public interest, and bonding.

On November 13, 2020, Rovi and Comcast filed a joint motion, including a memorandum in support thereof, to terminate the investigation based on a settlement agreement. There is no opposition to the motion from any party. Commission Rule 210.21(a)(2) states in relevant part that ''[a]ny party may move at any time for an order to terminate an investigation in whole or in part as to any or all respondents on the basis of a settlement, a licensing or other agreement . . . .'' 19 CFR 210.21(a)(2). Commission Rule 210.21(b) governs termination by settlement, and subsection (b)(1) provides that in order for an investigation to be terminated on the basis of a licensing or other settlement agreement, the motion for termination must include: (1) Copies of the ''licensing or other settlement agreement,'' including both a public and a confidential version if necessary; (2) any supplemental agreements; and (3) ''a statement that there are no other

agreements, written or oral, express or implied between the parties concerning the subject matter of the investigation.'' 19 CFR 210.21(b)(1).

Consistent with Commission Rule 210.21(b)(1), redacted versions of a patent license agreement and a settlement agreement between Rovi and Comcast were attached to the motion as Exhibits 1 and 2 and the unredacted agreements were filed separately under a confidential header. The moving parties submit that the agreements resolve the allegations of infringement against Comcast in the investigation. Motion at 1. In further compliance with Commission Rule 210.21(b)(1), the motion contains a statement that there are no other agreements, written or oral, express or implied between the parties concerning the subject matter of the investigation. *Id.* at 2. The movants submit that termination is in the interest of the public and administrative economy. *Id.* at 3.

Pursuant to Commission Rule 210.50(b)(2), the Commission finds no evidence that terminating this investigation will adversely affect the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive articles in the United States, or U.S. customers. 19 CFR 210.50(b)(2). Moreover, the public interest generally favors settlement to avoid needless litigation and to conserve public resources. *See, e.g., Certain Semiconductor Devices, Products Containing the Same, and Components Thereof (II),* Inv. No. 337–TA–1177, Order No. 5 at 2 (Nov. 25, 2019), *unreviewed by* Comm'n Notice (Dec. 20, 2019).

Accordingly, the Commission finds that the joint motion for termination satisfies Commission Rules 210.21(a)(2) and (b)(1) (19 CFR 210.21(a)(2), (b)(1)) and that termination of the investigation is not contrary to the public interest.

Accordingly, the Commission grants the joint motion to terminate the investigation in its entirety based on settlement. The investigation is terminated.

The Commission vote for this determination took place on November 30, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: November 30, 2020.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2020–26685 Filed 12–3–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–751]

Importer of Controlled Substances Application: Janssen Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Janssen Pharmaceuticals Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before January 4, 2021. Such persons may also file a written request for a hearing on the application on or before January 4, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on November 11, 2020, Janssen Pharmaceuticals Inc., 1440 Olympic Drive, Athens, Georgia 30601–1645, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Thebaine	9333	II
Poppy Straw Concentrate	9670	II
Tapentadol	9780	II

The company plans to import intermediate forms of Tapentadol (9780) and Thebaine (9333) for further manufacturing prior to distribution to its customers. The company plans to import Poppy Straw Concentrate (9670) to bulk manufacture other controlled substances. No other activity for these drug codes is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–26653 Filed 12–3–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the

Comprehensive Environmental Response, Compensation and Liability Act

On November 27, 2020, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of New Jersey in the lawsuit entitled *United States et al.* v. *Unimatic Manufacturing, Corp. et al.,* Civil Action No. 2:20-cv-17284.

The proposed Consent Decree would resolve claims the United States, New Jersey Department of Environmental Protection (''NJDEP'') and the Administrator of the New Jersey Spill Compensation Fund have brought pursuant to Section 107 of the Comprehensive Environmental Response, Compensation, and Liability

Act (''CERCLA''), 42 U.S.C. 9607 and the New Jersey Spill Compensation and Control Act, N.J.S.A. 58:10–23.11 to –23.24 against Defendants Unimatic Manufacturing Corporation, Cardean, LLC, Frameware, Inc., and Profiles, LLC concerning the Unimatic Manufacturing Superfund Site (''Site'') in Fairfield, New Jersey.

Under the proposed Consent Decree, former owner and operator Unimatic Manufacturing Corp. will pay $3,499,198.65 to the United States, $349,919.87 to the NJDEP, and $900,000 to Cardean, LLC. Current owner Cardean, LLC will maintain its property at the Site and sell it at the request of the United States, providing the proceeds to United States. In return for their payments and other requirements, Defendants receive covenants not to sue relating to the Site under Sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 & 9607, and for certain state cleanup costs.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States et al.* v. *Unimatic Manufacturing Corp. et al.,* D.J. Ref. No. 90–11–3–11559. All comments must be submitted no later than sixty (60) 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 e-mail	*pubcomment-ees.enrd@usdoj.gov*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611

Under section 7003(d) of RCRA, a commenter may request an opportunity for a public meeting in the affected area.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the 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.

Please enclose a check or money order for $20.00 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits, the cost is $8.25.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–26670 Filed 12–3–20; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0148]

Proposed Extension of Information Collection; Proximity Detection Systems for Continuous Mining Machines in Underground Coal Mines

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Proximity Detection Systems for Continuous Mining Machines in Underground Coal Mines.

DATES: All comments must be received on or before February 2, 2021.

ADDRESSES: You may submit comment as follows. Please note that late, untimely filed comments will not be considered.

Electronic Submissions: Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments for docket number MSHA–2020–0035. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket, with no changes. Because your comment will be made public, you are 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 your or anyone else's Social Security number or confidential business information.
- 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.

Written/Paper Submissions: Submit written/paper submissions in the following way:

- *Mail/Hand Delivery:* Mail or visit DOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452.
- MSHA will post your comment as well as any attachments, except for information submitted and marked as confidential, in the docket at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Roslyn B. Fontaine, Deputy Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813(h), authorizes MSHA to collect information necessary to carry out its duties in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811, authorizes the Secretary of Labor (Secretary) to develop, promulgate, and revise, as may be appropriate, mandatory health or safety standards for the protection of life and prevention of injuries in coal or other mines.

Under section 75.1732 of title 30 Code of Federal Regulations, MSHA requires underground coal mine operators to equip continuous mining machines, except full-face continuous mining machines, with proximity detection systems. Miners working near continuous mining machines face pinning, crushing, and striking hazards that result in accidents involving life-threatening injuries and death. Proximity detection is a technology that uses electronic sensors to detect the motion or the location of one object relative to another. Proximity detection systems provide a warning and stop continuous mining machines before a pinning, crushing, or striking accident occurs that could result in injury or death to a miner.

Section 75.1732(d)(1) requires at the completion of the check of the machine-mounted components of the proximity

detection system under section 75.1732(d)(1), a certified person under section 75.100 must certify by initials, date, and time that the check was conducted. Defects found as a result of the check, including corrective actions and dates of corrective actions, must be recorded before the end of the shift.

Section 75.1732(d)(2) requires the operator to make a record of the defects found as a result of the checks of miner-wearable components required under section 75.1732(c)(2), including corrective actions and dates of corrective actions.

Section 75.1732(d)(3) requires the operator to make a record of the persons trained in the installation and maintenance of proximity detection systems under section 75.1732(b)(6).

Section 75.1732(d)(4) requires the operator to maintain records in a secure book or electronically in a secure computer system not susceptible to alteration.

Section 75.1732(d)(5) requires the operator to retain records for at least 1 year and make them available for inspection by authorized representatives of the Secretary and representatives of miners.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Proximity Detection Systems for Continuous Mining Machines in Underground Coal Mines. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to 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.

Background documents related to this information collection request are available at *https://regulations.gov* and in DOL–MSHA located at 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION** section of this notice from the previous collection of information.

III. Current Actions

This information collection request concerns provisions for Proximity Detection Systems for Continuous Mining Machines in Underground Coal Mines. MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request from the previous information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0148.

Affected Public: Business or other for-profit.

Number of Respondents: 116.

Frequency: On occasion.

Number of Responses: 191,288.

Annual Burden Hours: 544 hours.

Annual Respondent or Recordkeeper Cost: $0.

Comments submitted in response to this notice will be summarized in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and will be available at *https://www.reginfo.gov.*

Roslyn B. Fontaine,

Certifying Officer.

[FR Doc. 2020–26740 Filed 12–3–20; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts, National Foundation on the Art and the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 10 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

DATES: See the **SUPPLEMENTARY INFORMATION** section for individual meeting times and dates. All meetings are Eastern time and ending times are approximate:

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW, Washington, DC, 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Sherry Hale, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *hales@arts.gov,* or call 202/682–5696.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of September 10, 2019, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

The Upcoming Meetings are

National Heritage Fellowships (review of applications): This meeting will be closed.

Date and time: January 12, 2021; 1:00 p.m. to 4:00 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time:January 12, 2021; 11:00 a.m. to 1:00 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: January 12, 2021; 2:30 p.m. to 4:30 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: January 13, 2021; 11:00 a.m. to 1:00 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: January 13, 2021; 2:30 p.m. to 4:30 p.m.

National Heritage Fellowships (review of applications): This meeting will be closed.

Date and time: January 14, 2021; 1:00 p.m. to 4:00 p.m.

Our Town (review of applications): This meeting will be closed.

Date and time: January 14, 2021; 2:30 p.m. to 4:30 p.m.

National Folklife Network (NFN) (review of applications): This meeting will be closed.

Date and time:January 21, 2021; 1:00 p.m. to 3:00 p.m.

Jazz Masters Fellowships (review of applications): This meeting will be closed.

Date and time: February 4, 2021; 2:00 p.m. to 3:00 p.m.

Jazz Masters Fellowships (review of applications): This meeting will be closed.

Date and time: February 4, 2021; 3:00 p.m. to 4:00 p.m.

Dated: December 1, 2020.

Sherry P. Hale,

Staff Assistant, National Endowment for the Arts.

[FR Doc. 2020–26720 Filed 12–3–20; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of November 30, December 7, 14, 21, 28, 2020, January 4, 11, 2021.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

Week of November 30, 2020

Friday, December 4, 2020

9:55 a.m. Affirmation Session (Public Meeting) (Tentative)

a. Interim Storage Partners, LLC (WCS Consolidated Interim Storage Facility), Appeal of LBP–19–11 (Denial of Motion to File Late Contention) (Tentative).

(Contact: Denise McGovern: 301–415–0681).

Additional Information: By a vote of 5–0 on December 1, 2020, the Commission determined pursuant to 5 U.S.C. 552b(e)(1) and 10 CFR 9.107 of the Commission's rules that the above referenced Affirmation Session be held with less than one week notice to the public. The meeting will be held on December 4, 2020. Due to COVID–19, there will be no physical public attendance. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://www.nrc.gov/.*

Friday, December 4, 2020

10:00 a.m. Meeting with Advisory Committee on Reactor Safeguards (Public Meeting)

(Contact: Larry Burkhart: 301–287–3775).

Additional Information: Due to COVID–19, there will be no physical public attendance.

The public is invited to attend the Commission's meeting live by webcast at the web address—*https://www.nrc.gov/.*

Week of December 7, 2020—Tentative

There are no meetings scheduled for the week of December 7, 2020.

Week of December 14, 2020—Tentative

There are no meetings scheduled for the week of December 14, 2020.

Week of December 21, 2020—Tentative

There are no meetings scheduled for the week of December 21, 2020.

Week of December 28, 2020—Tentative

There are no meetings scheduled for the week of December 28, 2020.

Week of January 4, 2021—Tentative

There are no meetings scheduled for the week of January 4, 2021.

Week of January 11, 2021—Tentative

There are no meetings scheduled for the week of January 11, 2021.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or by email at *Tyesha.Bush@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: December 2, 2020.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2020–26847 Filed 12–2–20; 4:15 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90530; File No. SR–CboeBZX–2020–085]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to List and Trade Shares of the Fidelity Growth Opportunities ETF, Fidelity Magellan ETF, Fidelity Real Estate Investment ETF, and Fidelity Small-Mid Cap Opportunities ETF Under Rule 14.11(m) (Tracking Fund Shares)

November 30, 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 November 24, 2020, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II 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 a rule change to list and trade shares of the Fidelity Growth Opportunities ETF, Fidelity Magellan ETF, Fidelity Real Estate Investment ETF, and Fidelity Small-Mid Cap Opportunities ETF (each a ''Fund'' and, collectively, the ''Funds''), each a series of the Fidelity Covington Trust (the ''Trust''), under Rule 14.11(m), Tracking Fund Shares. The shares of each Fund are referred to herein as the ''Shares.''

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 list and trade shares of each Fund pursuant to Rule 14.11(m), Tracking Fund Shares,[3] which are securities issued by an actively managed open-end management investment company.[4] The Exchange is submitting this proposal as required by Rule 14.11(m)(2)(A), which provides that the Exchange must file separate proposals under Section 19(b) of the Act before listing and trading of a series of Tracking Fund Shares.

The Shares will be offered by the Trust, which is organized as a business trust under the laws of The Commonwealth of Massachusetts. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Funds on Form N–1A with the Commission.[5] Fidelity Management & Research Company or FMR Co., Inc. (the ''Adviser'') will be the investment adviser to the Funds. The Adviser is not registered as a broker-dealer, but is affiliated with numerous broker-dealers. The Adviser represents that a fire wall exists and will be maintained between the respective personnel at the Adviser and affiliated broker-dealers with respect to access to information concerning the composition and/or changes to each Fund's portfolio and Tracking Basket.[6] Personnel who make decisions on a Fund's portfolio composition and/or Tracking Basket or who have access to nonpublic information regarding the Fund Portfolio [7] and/or the Tracking Basket or changes thereto are subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio and/or Tracking Basket. The Funds' sub-advisers, FMR Investment Management (UK) Limited, Fidelity Management & Research (Hong Kong) Limited, and Fidelity Management & Research (Japan) Limited (each a ''Sub-Adviser'' and, collectively, the ''Sub-Advisers''), are not registered as a broker-dealer but are affiliated with numerous broker-dealers. Sub-Adviser personnel who make decisions regarding a Fund's Fund Portfolio and/or Tracking Basket or who have access to information regarding the Fund Portfolio and/or the Tracking Basket or changes thereto are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio and/or Tracking Basket. In the event that (a) the Adviser or a Sub-Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer; or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes newly affiliated with a broker-dealer; it will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the Fund Portfolio and/or Tracking Basket, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio and/or Tracking Basket. Any person or entity, including any service provider for the Funds, who has access to nonpublic information regarding a Fund Portfolio or Tracking Basket or changes thereto for a Fund or Funds will be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Fund Portfolio or Tracking Basket or changes thereto. Further, any such person or entity that is registered as a broker-dealer or affiliated with a broker-dealer, has erected and will maintain a ''fire wall'' between the person or entity and the broker-dealer with respect to access to information concerning the composition and/or changes to such Fund Portfolio or Tracking Basket. Each Fund intends to qualify each year as a regulated investment company under Subchapter M of the Internal Revenue Code of 1986, as amended.

The Shares will conform to the initial and continued listing criteria under Rule 14.11(m) as well as all terms in the Exemptive Order. The Exchange represents that, for initial and/or continued listing, each Fund will be in compliance with Rule 10A–3 under the Act.[8] A minimum of 100,000 Shares of each Fund will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares of each Fund that the NAV per share of each Fund will be calculated daily and will be made available to all market participants at the same time. Each Fund's investments will be consistent with its investment objective and will not be used to enhance leverage.

Fidelity Growth Opportunities ETF

The Fund's holdings will conform to the permissible investments as set forth in the Exemptive Relief and the holdings will be consistent with all requirements in the Exemptive Relief.[9]

[3] As defined in Rule 14.11(m)(3)(A), the term ''Tracking Fund Share'' means a security that: (i) Represents an interest in an investment company (''Investment Company'') registered under the Investment Company Act of 1940 (the ''1940 Act'') organized as an open-end management investment company, that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; (ii) is issued in a specified aggregate minimum number in return for a deposit of a specified Tracking Basket and/or a cash amount with a value equal to the next determined Net Asset Value (''NAV''); (iii) when aggregated in the same specified minimum number, may be redeemed at a holder's request, which holder will be paid a specified Tracking Basket and/or a cash amount with a value equal to the next determined NAV; and (iv) the portfolio holdings for which are disclosed within at least 60 days following the end of every fiscal quarter.

[4] Rule 14.11(m) was approved along with the listing and trading of three series of Tracking Fund Shares by the Commission on May 15, 2020. *See* Securities Exchange Act Release No. 88887 (May 15, 2020), 85 FR 30990 (May 21, 2020) (the ''Tracking Fund Shares Approval Order'').

[5] The Trust is registered under the 1940 Act. On September 24, 2020, the Trust filed a registration statement on Form N–1A relating to the Funds (File No. 811–07319) (the ''Registration Statement''). The descriptions of the Funds and the Shares contained herein are based, in part, on information included in the Registration Statement. The Commission has issued an order granting certain exemptive relief under the Investment Company Act of 1940 (15 U.S.C. 80a–1) to Fidelity Management & Research Company and FMR Co., Inc., Fidelity Beach Street Trust, and Fidelity Distributors Corporation (File No. 812–14364), issued on December 10, 2019 (the ''Application,'' ''Notice,'' and ''Order,'' respectively, and, collectively, the ''Exemptive Order''). *See* Investment Company Act Release Nos. 33683 (November 14, 2019), 84 FR 64140 (November 20, 2019) (the Notice) and 33712 (the Order).

[6] As defined in Rule 14.11(m)(3)(E), the term ''Tracking Basket'' means the identities and quantities of the securities and other assets included in a basket that is designed to closely track the daily performance of the Fund Portfolio, as provided in the exemptive relief under the 1940 Act applicable to a series of Tracking Fund Shares.

[7] As defined in Rule 14.11(m)(3)(B), the term ''Fund Portfolio'' means the identities and quantities of the securities and other assets held by the Investment Company that will form the basis for the Investment Company's calculation of net asset value at the end of the business day.

[8] *See* 17 CFR 240.10A–3.

[9] Pursuant to the Exemptive Relief, the Fund's permissible investments include only the following instruments: ETFs, exchange-traded notes, exchange-traded common stocks, common stocks listed on a foreign exchange that trade on such exchange contemporaneously with the Shares (''foreign common stocks''), exchange-traded preferred stocks, exchange-traded American Depositary Receipts (''ADRs''), exchange-traded real estate investment trusts, exchange-traded commodity pools, exchange-traded metals trusts, exchange-traded currency trusts, and exchange-traded futures that trade contemporaneously with the Shares, as well as cash and cash equivalents.

Continued

Any foreign common stocks held by the Fund will be traded on an exchange that is a member of the Intermarket Surveillance Group (''ISG'')[10] or with which the Exchange has in place a comprehensive surveillance sharing agreement.

The Fund seeks long-term growth of capital. In order to achieve its investment objective, the Fund typically invests primarily in equity securities of domestic and foreign issuers that the Adviser believes have above-average growth potential, as determined using fundamental analysis of factors such as each issuer's financial condition and industry position, as well as market and economic conditions.

Fidelity Magellan ETF

The Fund's holdings will conform to the permissible investments as set forth in the Exemptive Relief and the holdings will be consistent with all requirements in the Exemptive Relief.[11] Any foreign common stocks held by the Fund will be traded on an exchange that is a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[12]

The Fund seeks long-term growth of capital. In order to achieve its investment objective, the Fund typically invests primarily in equity securities of domestic and foreign issuers that, based on fundamental analysis of factors such as each issuer's financial condition and industry position, as well as market and economic conditions, the Adviser believes are ''growth'' stocks or ''value'' stocks or both.

Fidelity Real Estate Investment ETF

The Fund's holdings will conform to the permissible investments as set forth in the Exemptive Relief and the holdings will be consistent with all requirements in the Exemptive Relief.[13] Any foreign common stocks held by the Fund will be traded on an exchange that is a member of the Intermarket Surveillance Group (''ISG'')[14] or with which the Exchange has in place a comprehensive surveillance sharing agreement.

The Fund seeks above-average income and long-term capital growth, consistent with reasonable investment risk. In order to achieve its investment objective, the Fund normally invests at least 80% of assets in securities of companies principally engaged in the real estate industry and other real estate related investments. Such investments are primarily in equity securities of domestic and foreign issuers based on fundamental analysis of factors such as each issuer's financial condition and industry position, as well as market and economic conditions.

Fidelity Small-Mid Cap Opportunities ETF

The Fund's holdings will conform to the permissible investments as set forth in the Exemptive Relief and the holdings will be consistent with all requirements in the Exemptive Relief.[15] Any foreign common stocks held by the Fund will be traded on an exchange that is a member of the Intermarket Surveillance Group (''ISG'')[16] or with which the Exchange has in place a comprehensive surveillance sharing agreement.

The Fund seeks long-term growth of capital. In order to achieve its investment objective, the Fund normally invests at least 80% of assets in securities of companies with small to medium market capitalizations (which, for purposes of this fund, are those companies with market capitalizations similar to companies in the Russell 2500™ Index) by investing in domestic and foreign issuers that, based on fundamental analysis of factors such as each issuer's financial condition and industry position, as well as market and economic conditions, the Adviser believes are ''growth'' stocks or ''value'' stocks or both.

Trading Halts

Rule 14.11(m)(4)(B)(iv) provides that (a) the Exchange may consider all relevant factors in exercising its discretion to halt trading in a series of Tracking Fund Shares. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (i) The extent to which trading is not occurring in the securities and/or the financial instruments composing the Tracking Basket or Fund Portfolio; or (ii) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present; and (b) if the Exchange becomes aware that one of the following is not being made available to all market participants at the same time: The net asset value, the Tracking Basket, or the Fund Portfolio with respect to a series of Tracking Fund Shares, then the Exchange will halt trading in such series until such time as the net asset value, the Tracking Basket, or the Fund Portfolio is available to all market participants, as applicable.

Trading Rules

The Exchange deems Tracking Fund Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities.[17] As provided in Rule

With the exception of foreign common stocks and cash and cash equivalents, all holdings of the Fund will be listed on a U.S. national securities exchange.

[10] For a list of the current members of ISG, *see www.isgportal.com.* The Exchange notes that all components, except the cash and cash equivalent components, of the Funds may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[11] Pursuant to the Exemptive Relief, the Fund's permissible investments include only the following instruments: ETFs, exchange-traded notes, exchange-traded common stocks, foreign common stocks, exchange-traded preferred stocks, ADRs, exchange-traded real estate investment trusts, exchange-traded commodity pools, exchange-traded metals trusts, exchange-traded currency trusts, and exchange-traded futures that trade contemporaneously with the Shares, as well as cash and cash equivalents. With the exception of foreign common stocks and cash and cash equivalents, all holdings of the Fund will be listed on a U.S. national securities exchange.

[12] For a list of the current members of ISG, *see www.isgportal.com.* The Exchange notes that all components, except the cash and cash equivalent components, of the Funds may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[13] Pursuant to the Exemptive Relief, the Fund's permissible investments include only the following instruments: ETFs, exchange-traded notes, exchange-traded common stocks, foreign common stocks, exchange-traded preferred stocks, ADRs, exchange-traded real estate investment trusts, exchange-traded commodity pools, exchange-traded metals trusts, exchange-traded currency trusts, and exchange-traded futures that trade contemporaneously with the Shares, as well as cash and cash equivalents. With the exception of foreign common stocks and cash and cash equivalents, all holdings of the Fund will be listed on a U.S. national securities exchange.

[14] For a list of the current members of ISG, *see www.isgportal.com.* The Exchange notes that all components, except the cash and cash equivalent components, of the Funds may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[15] Pursuant to the Exemptive Relief, the Fund's permissible investments include only the following instruments: ETFs, exchange-traded notes, exchange-traded common stocks, foreign common stocks, exchange-traded preferred stocks, ADRs, exchange-traded real estate investment trusts, exchange-traded commodity pools, exchange-traded metals trusts, exchange-traded currency trusts, and exchange-traded futures that trade contemporaneously with the Shares, as well as cash and cash equivalents. With the exception of foreign common stocks and cash and cash equivalents, all holdings of the Fund will be listed on a U.S. national securities exchange.

[16] For a list of the current members of ISG, *see www.isgportal.com.* The Exchange notes that all components, except the cash and cash equivalent components, of the Funds may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[17] With respect to trading in Tracking Fund Shares, all of the BZX Member obligations relating to product description and prospectus delivery requirements will continue to apply in accordance

14.11(m)(2)(C), the minimum price variation for quoting and entry of orders in securities traded on the Exchange is $0.01. The Exchange has appropriate rules to facilitate trading in Tracking Fund Shares during all trading sessions.

Tracking Basket for the Proposed Funds

For the Funds, the Tracking Basket will consist of a combination of the Fund's recently disclosed portfolio holdings and representative ETFs. The Exchange notes that the Tracking Basket methodology used by the Fund is substantively identical to a proposal previously approved by the Commission.[18] ETFs selected for inclusion in the Tracking Basket will be consistent with the Fund's objective and selected based on certain criteria, including, but not limited to, liquidity, assets under management, holding limits and compliance considerations. Representative ETFs can provide a useful mechanism to reflect a Fund's holdings' exposures within the Tracking Basket without revealing a Fund's exact positions.[19] Intraday pricing information for all constituents of the Tracking Basket that are exchange-traded, which includes all eligible instruments except cash and cash equivalents, will be available on the exchanges on which they are traded and through subscription services. Intraday pricing information for cash equivalents will be available through subscription services and/or pricing services. The Exchange notes that each Fund's NAV will form the basis for creations and redemptions for the Funds and creations and redemptions will work in a manner substantively identical to that of series of Managed Fund Shares. The Adviser expects that the Shares of the Funds will generally be created and redeemed in-kind, with limited exceptions. The names and quantities of the instruments that constitute the basket of securities for creations and redemptions will be the same as a Fund's Tracking Basket, except to the extent purchases and redemptions are made entirely or in part on a cash basis. In the event that the value of the Tracking Basket is not the same as a Fund's NAV, the creation and redemption baskets will consist of the securities included in the Tracking Basket plus or minus an amount of cash equal to the difference between the NAV and the value of the Tracking Basket, as further described below.

The Tracking Basket will be constructed utilizing a covariance matrix based on an optimization process to minimize deviations in the return of the Tracking Basket relative to the Fund. The proprietary optimization process mathematically seeks to minimize three key parameters that the Adviser believes are important to the effectiveness of the Tracking Basket as a hedge: Tracking error (standard deviation of return differentials between the Tracking Basket and the Fund), turnover cost, and basket creation cost.[20] Typically, the Tracking Basket is expected to be rebalanced on schedule with the public disclosure of the Fund's holdings; however, a new optimized Tracking Basket may be generated as frequently as daily, and therefore, rebalancing may occur more frequently at the Adviser's discretion. In determining whether to rebalance a new optimized Tracking Basket, the Adviser will consider various factors, including liquidity of the securities in the Tracking Basket, tracking error, and the cost to create and trade the Tracking Basket.[21] For example, if the Adviser determines that a new Tracking Basket would reduce the variability of return differentials between the Tracking Basket and the Fund when balanced against the cost to trade the new Tracking Basket, rebalancing may be appropriate. The Adviser will periodically review the Tracking Basket parameters and Tracking Basket performance and process.

As noted above, each Fund will also disclose the entirety of its portfolio holdings, including the name, identifier, market value and weight of each security and instrument in the portfolio, at a minimum within at least 60 days following the end of every fiscal quarter. The Exchange notes that the concept of the Tracking Basket employed under this structure is designed to provide investors with the traditional benefits of ETFs while protecting the Funds from the potential for front running or free riding of portfolio transactions, which could adversely impact the performance of a Fund.

The Exchange believes that the particular instruments that may be included in each of the Fund's respective Fund Portfolio and Tracking Basket do not raise any concerns related to the Tracking Baskets being able to closely track the NAV of the Funds because such instruments include only instruments that trade on an exchange contemporaneously with the Shares.[22] In addition, each Fund's Tracking Basket will be optimized so that it reliably and consistently correlates to the performance of the Fund.

The Adviser anticipates that the returns between a Fund and its respective Tracking Basket will have a consistent relationship and that the deviation in the returns between a Fund and its Tracking Basket will be sufficiently small such that the Tracking Basket will provide authorized participants, arbitrageurs, and certain other market participants (collectively, ''Market Makers'') with a reliable hedging vehicle that they can use to effectuate low-risk arbitrage trades in Fund Shares. The Exchange believes that the disclosures provided by the Funds will allow Market Makers to understand the relationship between the performance of a Fund and its Tracking Basket. Market Makers will be able to estimate the value of and hedge positions in a Fund's Shares, which the Exchange believes will facilitate the arbitrage process and help ensure that the Fund's Shares normally will trade at market prices close to their NAV. The Exchange also believes that competitive market making, where traders are looking to take advantage of differences in bid-ask spread, will aid in keeping spreads tight.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[23] in general and Section 6(b)(5) of the Act[24] in particular in that

with Exchange rules and federal securities laws, and the Exchange will continue to monitor its Members for compliance with such requirements.

[18] *See* Tracking Fund Shares Approval Order.

[19] The set of ETFs that are ''representative'' to be used in the Tracking Basket will depend on certain factors, including the Fund's investment objective, past holdings, and benchmark, and may change from time to time. For example, a U.S. diversified fund benchmarked to a diversified U.S. index would use liquid U.S. exchange-traded ETFs to capture size (large, mid or small capitalization), style (growth or value) and/or sector exposures in the Fund's portfolio. Leveraged and inverse ETFs will not be included in the Tracking Basket. ETFs may constitute no more than 50% of the Tracking Basket's assets.

[20] Tracking error measures the deviations between the Tracking Basket and Fund. Turnover cost and basket creation cost are measures of the cost to create and maintain the Tracking Basket as a hedge.

[21] The Adviser uses a trading cost model to develop estimates of costs to trade a new Tracking Basket. There are essentially two elements to this cost: (1) The cost to purchase securities constituting the Tracking Basket, *i.e.,* the cost to put on the hedge for the Authorized Participant, and (2) the cost of any adjustments that need to be made to the composition of the Tracking Basket, *i.e.,* the cost to the Authorized Participant to change or maintain the hedge position. The inclusion of the trading cost model in the optimization process is intended to result in a Tracking Basket that is cost effective and liquid without compromising its tracking ability.

[22] The Exchange notes that to the extent that the Fund Portfolio or Tracking Basket include any foreign common stocks, such securities will be traded on an exchange that is a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[23] 15 U.S.C. 78f.

[24] 15 U.S.C. 78f(b)(5).

it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, 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 notes that a significant amount of information about each Fund and its Fund Portfolio will be publicly available at all times. Each Fund will disclose the Tracking Basket, which is designed to closely track the daily performance of the Fund Portfolio, on a daily basis. Each Fund will at a minimum publicly disclose the entirety of its portfolio holdings, including the name, identifier, market value and weight of each security and instrument in the portfolio within at least 60 days following the end of every fiscal quarter in a manner consistent with normal disclosure requirements otherwise applicable to open-end investment companies registered under the 1940 Act. The website will include additional quantitative information updated on a daily basis, including, on a per Share basis for each Fund, the prior business day's NAV and the closing price or bid/ask price at the time of calculation of such NAV, and a calculation of the premium or discount of the closing price or bid/ask price against such NAV. The website will also disclose the percentage weight overlap between the holdings of the Tracking Basket compared to the Fund Holdings for the prior business day and any information regarding the bid/ask spread for each Fund as may be required for other ETFs under Rule 6c–11 under the 1940 Act, as amended. Price information for the exchange-listed instruments held by the Funds, including both U.S. and non-U.S. listed equity securities and U.S. exchange-listed futures will be available through major market data vendors or securities exchanges listing and trading such securities.

The Exchange represents that the Shares of the Funds will continue to comply with all other requirements applicable to Tracking Fund Shares, including the dissemination of key information such as the Tracking Basket, the Fund Portfolio, and NAV, suspension of trading or removal, trading halts, surveillance, minimum price variation for quoting and order entry, an information circular informing members of the special characteristics and risks associated with trading in the Shares, and firewalls as set forth in the Rules applicable to Tracking Fund Shares and the order approving such rules. Moreover, U.S.-listed equity securities held by the Funds will trade on markets that are a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[25] All statements and representations made in this filing regarding the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of reference asset (as applicable), or the applicability of Exchange listing rules specified in this filing shall constitute continued listing requirements for the Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by a Fund or Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. FINRA conducts certain cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement. If a Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures with respect to such Fund under Exchange Rule 14.12.

The Exchange believes that the proposal is designed to prevent fraudulent and manipulative acts and practices in that the Rules relating to listing and trading of Tracking Fund Shares provide specific initial and continued listing criteria required to be met by such securities.

Rules 14.11(m)(4)(B)(iii) and (iv) provide that the Exchange will consider the suspension of trading in and will commence delisting proceedings for a Fund pursuant to Rule 14.12 under any of the circumstances described above and that the Exchange may consider all relevant factors in exercising its discretion to halt trading in a series of Tracking Fund Shares. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

Additionally, the Exchange believes that the requirements related to information protection enumerated under Rule 14.11(m)(2)(F) will act as a strong safeguard against any misuse and improper dissemination of information related to a Fund Portfolio, the Tracking Basket, or changes thereto. The requirement that any person or entity, including a custodian, Reporting Authority, distributor, or administrator, who has access to nonpublic information regarding the Fund Portfolio or the Tracking Basket or changes thereto, must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable Fund Portfolio or the Tracking Basket or changes thereto will act to prevent any individual or entity from sharing such information externally.

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the 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 the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Tracking Fund Shares. If a Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees. Any foreign common stocks held by the Fund will be traded on an exchange that is a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. All futures contracts that the Funds may invest in will be traded on a U.S. futures exchange. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, underlying U.S. exchange-listed equity securities, and U.S. exchange-listed futures with other markets and other entities that are members of ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading such instruments from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, underlying equity securities, and U.S. exchange-listed futures from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

As provided in Rule 14.11(m)(2)(D), the Adviser will upon request make available to the Exchange and/or FINRA, on behalf of the Exchange, the daily Fund Portfolio of each Fund. The Exchange believes that the ability to access the information on an as needed basis will provide it with sufficient

[25] See supra note 10.

information to perform the necessary regulatory functions associated with listing and trading the Shares on the Exchange, including the ability to monitor compliance with the initial and continued listing requirements as well as the ability to surveil for manipulation of the Shares.

In addition, Form N–PORT requires reporting of a fund's complete portfolio holdings on a position-by-position basis on a quarterly basis within 60 days after fiscal quarter end. Investors can obtain a fund's Statement of Additional Information, its Shareholder Reports, its Form N–CSR, filed twice a year, and its Form N–CEN, filed annually. A fund's SAI and Shareholder Reports are available free upon request from the Investment Company, and those documents and the Form N–PORT, Form N–CSR, and Form N–CEN may be viewed on-screen or downloaded from the Commission's website at *www.sec.gov.* The Exchange also notes that the Exemptive Relief provides that the Funds will comply with Regulation Fair Disclosure, which prohibits selective disclosure of any material non-public information, which otherwise do not apply to issuers of Tracking Fund Shares.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via the CTA high-speed line. The Exchange deems Tracking Fund Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. As provided in Rule 14.11(m)(2)(C), the minimum price variation for quoting and entry of orders in securities traded on the Exchange is $0.01.

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. Rather, the Exchange notes that the proposed rule change will facilitate the listing of several new series of actively-managed exchange-traded product, thus enhancing 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 has neither solicited nor received written 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 [26] and Rule 19b–4(f)(6) thereunder.[27]

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.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2020–085 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2020–085. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2020–085 and should be submitted on or before December 28, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26675 Filed 12–3–20; 8:45 am]

BILLING CODE 8011–01–P

[26] 15 U.S.C. 78s(b)(3)(A).

[27] 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.

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90534; File No. SR–DTC–2020–017]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Proposed Rule Change to Allow for the Deposit of Electronic Certificates of Deposit and Technical Changes

November 30, 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 November 20, 2020, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change[3] consists of amendments to the Procedures[4] of DTC. Specifically, the proposed rule change would amend the OA and Underwriting Service Guide to implement a new application and secured electronic vault (''E-vault'') for requests for eligibility, execution, Delivery and storage of certificates of deposit (''CDs'') that are issued by state and federal chartered banks that are Eligible Securities[5] in electronic form. Technical changes with respect to spelling, punctuation and spacing of text would also be made. The use of the new application and E-vault would replace an existing legacy platform and paper-based model for Delivery and storage of CDs maintained in DTC's secured physical vault, as more fully described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The proposed rule change of DTC would amend the Procedures of DTC. Specifically, the proposed rule change would amend the OA and Underwriting Service Guide to implement a new application and secured E-vault for requests for eligibility, execution, Delivery and storage of CDs that are (i) Eligible Securities and (ii) issued by state and federal chartered banks in electronic form. The use of the new application and E-vault would replace an existing legacy platform for Delivery and storage of CDs maintained in DTC's secured physical vault, as more fully described below.

Background

DTC (i) makes eligible for Deposit, processes and holds physical retail CDs issued by various U.S. banks and Deposited by Participants and (ii) credits interests in those CDs to Participant's Securities Accounts.[6] As described below, the use of physical certificates presents operational concerns to Participants and to DTC and DTC has undertaken efforts to promote dematerialization of Securities. To address operational concerns relating to processing of physical CDs, DTC has developed a system that would eliminate the need for physical certificates for certain issue types of CDs by allowing them to be issued and held in electronic form, as described below.

Upon implementation, the proposed rule change would address operational concerns of Participants relating to the amount of time and manual effort currently required for the issuance and redemption of physical CDs by allowing for a fully electronic process for the execution and Delivery of the affected CD certificates. As such, the proposed rule change would also reduce the need for DTC to (i) perform manual processing relating to CD Deposits and (ii) reserve space in its secure physical vault currently used for CDs by allowing for the storage of CDs in electronic form in a secure E-vault.

The proposed electronic process would also address concerns relating to potential disruptions in the physical transport of paper CDs to DTC currently made using courier and overnight delivery services. Such disruptions may be caused by weather-related issues, such as Superstorm Sandy which impacted physical securities processing in 2012, and other previously unforeseen circumstances, such as the COVID–19 pandemic. Although, DTC has been able to maintain securities eligibility and processing operations during such circumstances, including by utilizing a letter of securities possession[7] (''LOP'') process that enables DTC to accept Delivery of securities represented in physical form even if the circumstances prevent physical delivery at that time, such disruptions could delay the Deposit of CDs and impact the timely closing of issuances and otherwise affect liquidity in the marketplace for CDs.

Current DTC Eligibility Process for CDs

Only Participants can request that DTC make a Security eligible for Deposit.[8] It is therefore incumbent on an issuer to have a relationship with an underwriter or other financial institution that is a Participant, or is directly associated with a Participant, that is willing to sponsor the eligibility process for the issuer's Securities.[9] A Participant may submit a Deposit eligibility request for a CD through the underwriting services of DTC at the time a security is initially being offered and distributed to the marketplace or at a later time for already issued and outstanding securities.[10]

Participants must provide an eligibility request for the specified securities to Underwriting by submitting all required issuer and securities data and all related offering documents, at a minimum, through the online Securities Origination, Underwriting and Reliable Corporate Action Environment (''UW SOURCE'') system.[11]

CDs are book entry-only (''BEO'') Securities[12] registered to DTC's

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Capitalized terms not defined herein are defined in the Rules, By-Laws and Organization Certificate of DTC (the ''Rules''), *available at www.dtcc.com/~/media/Files/Downloads/legal/rules/dtc_rules.pdf,* the DTC Operational Arrangements (Necessary for Securities to Become and Remain Eligible for DTC Services) (''OA''), *available at http://www.dtcc.com/~/media/Files/Downloads/legal/issue-eligibility/eligibility/operational-arrangements.pdf,* and the DTC Underwriting Service Guide (''Underwriting Service Guide''), *available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Underwriting-Service-Guide.pdf.*

[4] The OA and the Underwriting Service Guide constitute Procedures of DTC. Pursuant to the Rules, the term ''Procedures'' means the Procedures, service guides, and regulations of DTC adopted pursuant to Rule 27, as amended from time to time. *See* Rule 1, Section 1, *supra* note 3. DTC's Procedures are filed with the Commission. They are binding on DTC and each Participant in the same manner as they are bound by the Rules. *See* Rule 27, *supra* note 3. The OA is also binding on each issuer and agent of an Eligible Security. *See* OA, *supra* note 3 at 5, *supra* note 3. DTC also maintains service guides that constitute Procedures relating to services it offers. *Available at http://www.dtcc.com/legal/rules-and-procedures?subsidiary=DTC&pgs=1.*

[5] Generally, Eligible Securities must have been issued in a transaction (i) registered with the Commission pursuant to the Securities Act; (ii) exempt from registration pursuant to a Securities Act exemption without transfer or ownership restrictions; or (iii) pursuant to Rule 144A, 17 CFR 230.144A, or Regulation S, 17 CFR 230.901–230.905, under the Securities Act. *See* OA, *supra* note 3 at 2–3.

[6] *See* OA, *supra* note 3, at 9–10.

[7] *See* Underwriting Service Guide, *supra* note 3 at 17.

[8] *See id.* at 1.

[9] *Id.*

[10] *Id.*

[11] *Id.* at 2.

[12] *Id.* at 4.

nominee, Cede & Co. BEO Securities are DTC-eligible Securities for which (i) physical certificates are not available to investors and (ii) DTC, through its nominee, Cede & Co., will hold the entire balance of the offering, either at DTC (in physical form) or through a FAST Agent in DTC's Fast Automated Securities Transfer (''FAST'') program. Issuers of BEO Securities must submit to DTC a Letter of Representations (''LOR'') among the issuer, its agent (as applicable) and DTC, prior to such issue being determined to be eligible. For corporate and municipal securities, there are two acceptable forms of LOR: A Blanket Issuer Letter of Representations (''BLOR'') or an Issuer Letter of Representations (''ILOR''). A BLOR is issuer specific and applicable to all DTC-eligible securities (debt and/or equity) of the same issuer. Once a BLOR is on file for an issuer, a new BLOR is not required for future issuances unless the issuer's name changes (in which case an opinion of counsel may also be required). An ILOR may be used for discrete issuances, and is applicable only to that issue of securities, such as trust issuances. Each issuer of a BEO Security must submit to DTC a fully executed LOR on DTC's preprinted form. This LOR represents the issuer's agreement to comply with the requirements set forth in the OA, as amended from time to time.[13]

Once DTC has determined to make a Security eligible, a Participant may Deposit the Security at DTC for crediting to its Securities Account. For a CD issuance, the issuing bank and Depositing Participant must coordinate the execution and Delivery of the physical certificate to DTC in order for the Participant to timely receive credit by the anticipated closing date.[14] Once DTC receives an acceptable Deposit of an eligible CD from a Participant, DTC credits a Security Entitlement[15] in the CD to the Participant's Securities Account[16] and DTC holds the original paper certificate in its secure vault for the duration of the term of the CD.

Proposal

Pursuant to the proposed rule change, DTC is proposing to launch a new program to support Deposit of electronic CDs that would be issued by banks (''E–CDs''). The program would allow E–CDs to be electronically generated, signed, delivered to DTC and held in electronic form in a secure E-vault.

Upon implementation of the proposed rule change, CDs of state and federally chartered banks containing certain standard terms that conform to one of four proposed templates (''System E–CD Templates'') would be eligible for the new program, as described below. The System E–CD Templates were developed with input from DTC Participants that act as underwriters of CD. The templates would cover four basic types of CDs, specifically (i) Fixed Rate Non-Callable, (ii) Fixed Rate Callable, (iii) Step Rate Non-Callable and (iv) Step Rate Callable.[17]

After implementation, in order to facilitate needs of issuers and underwriters, DTC may, at its own discretion, (i) edit the System E–CD Templates and/or (ii) add additional templates for use in the E–CD program as published via Important Notice that would also be deemed System E–CD Templates. Any edits to the System E–CD Templates would not affect E–CDs that were previously issued into DTC.

More complex CDs that do not conform to the System E–CD Templates, including those referred to as structured CDs, would be excluded from the proposed new process, because they typically contain terms that are not amenable to the creation of fixed templates in the format proposed herein.

Upon implementation, Participants would request eligibility for E–CDs that conform to the System E–CD Templates through a new system referred to as Underwriting Central (''UWC''). UW SOURCE would continue to remain available for other types of issuances, including the issuances of CDs in physical form.

In order to request eligibility of a CD to be issued in electronic form, the Underwriter would provide all required information relating to the CD through UWC, including but not limited to offering documentation and the terms to be populated in the electronic certificate. The relevant data (*e.g.,* interest rate(s) and maturity date) will be populated into the templates as entered by the underwriter into the UWC application. It would be the responsibility of the Underwriter to disseminate the electronic master certificate to the issuer for electronic signature via UWC. The issuer would be required to electronically sign and Deliver the master certificate to DTC prior to closing.

For CDs that do not conform to the System E–CD Templates, eligibility request would continue to be entered by the Underwriter through UW SOURCE and a physical certificate delivered to DTC prior to closing.

Whether issued in electronic or physical form, securities should be delivered to DTC by no later than noon Eastern Time on the business day prior to the Closing Date as currently specified in Exhibit B of the OA.

In addition, each issuer that opts to issue E–CDs would be required to provide a new BLOR designed for use with the E–CD program, as described below.

Legal Framework Supporting Issuance of Electronic CDs

The following discussion is provided by DTC and includes its own analysis of applicable state law provisions that DTC believes supports the validity of the issuance and Deposit of E–CDs at DTC pursuant to the proposed rule change. Based on its analysis, DTC believes that the proposed rule change would allow E–CDs to be electronically generated, signed, Delivered to DTC and held in electronic form in a secure E-vault within a legal framework that supports the validity of E–CDs in a manner comparable to that of physical issuance and Deposit of CDs that are eligible for DTC services pursuant to the Rules and Procedures. This analysis is not part of the proposed rule, but a separate, analysis of applicable law. DTC emphasizes that neither the following, nor any aspect of the proposed rule change, is intended by DTC to be legal advice by DTC to any Participant, issuer or other third party, and should not be considered to be legal advice by DTC to any Participant, issuer, or other third party.

[13] *Id.*

[14] *See* DTC Deposits Service Guide (''Deposits Guide''), *available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Deposits.pdf,* at 8. The closing date is the date on which Underwriting will distribute an issue to the underwriter's Participant account at DTC for book-entry delivery and settlement upon notification by both the underwriter and the issuer that an issue has closed (*i.e.,* the distribution date). *See* Underwriting Guide, *supra* note 3, at 6. On the closing date, when an issuer or its agent and the underwriter confirm with DTC that the issue has closed and verifies pertinent data, DTC releases the position from an internal DTC account and credits the underwriter's Participant account, provided that DTC received the certificates. *See id.* at 9.

[15] Pursuant to Rule 1, the term ''Security Entitlement'' has the meaning given to the term ''security entitlement'' in Section 8–102 of the New York Uniform Commercial Code (''NYUCC''). *See* Rule 1, *supra* note 3. *See also* NYUCC 8–102. The interest of a Participant or Pledgee in a Security credited to its Account is a Security Entitlement. *See* Rule 1, *supra* note 3.

[16] *See* Deposits Guide, *supra* note 14, at 8.

[17] A Fixed Rate CD pays a fixed interest rate over the entire term of the CD. A Step Rate CD allows for increases in the interest rate at specific, intervals that are pre-defined by the issuer. A Callable CD contains a call feature that gives the issuing bank the ability to redeem the CD prior to its stated maturity, usually within a given time frame and at a preset call price as set forth in the ''call provision'' in the master certificate. A certificate without such a provision cannot not be called by the issuer prior to maturity date (Non-Callable).

DTC's Rules are Governed by the Law of New York

DTC's activities and its Rules are structured in accordance with the laws of New York and the United States, and provide that they shall be governed by, and construed in accordance with, the law of New York.[18] A principal law comprising the legal framework under which DTC operates includes, but is not limited to, the NYUCC, which among other things, supports a legal framework for the issuance of Securities and the indirect holding system, under which DTC credits in Securities to its Participants.

NYUCC and Electronic Signature Laws; and Impact Regarding E–CDs

CDs are ''negotiable instruments'' under Article 3 of the Uniform Commercial Code (the ''UCC''),[19] which has been adopted in New York under the NYUCC,[20] and, depending on how they are structured, may also be ''securities'' and/or ''financial assets,'' as defined in Article 8 of the UCC, which has been adopted in New York under the NYUCC.[21] In addition, because the CDs are held in DTC through the indirect holding system, the rights and duties of DTC, as a securities intermediary, and its Participants, as entitlement holders, are governed by Part 5 of Article 8 of the UCC,[22] also adopted in New York under the NYUCC. In this regard, the rights and obligations associated with CDs held at DTC are governed by the relevant provisions of the NYUCC.

Section 8–110 of the UCC provides that only the law of the issuer's jurisdiction will govern the ''validity'' of a ''security''—the laws of another jurisdiction cannot be selected to govern validity issues. The term ''validity'' is not defined in the UCC. DTC believes that laws governing the creation and existence of an electronic record as a substitute for a written instrument may be viewed as laws that govern the ''validity'' of an instrument.[23]

An E–CD that is both a negotiable instrument and a security, will be governed as to its validity by the law of the issuer's jurisdiction, by virtue of Section 8–110 of the UCC. If the validity of a security is determined to include its electronic nature, then the electronic signature and record laws of each individual issuer's jurisdiction would apply to each E–CD. Therefore, requiring an E–CD to be a security could adversely impact the valid issuance of the E–CD if the laws of the issuer's jurisdiction do not contemplate the electronic signature of a security.

However, as discussed below, Article 3 negotiable instruments allow for a choice of law. In this regard, DTC believes that requiring E–CDs to be issued as negotiable instruments would facilitate the valid issuance of E–CDs regardless of an issuer's jurisdiction, so long as the law of a jurisdiction that contemplates the use of electronic signatures as part of a valid issuance is chosen to govern the E–CD.

As more fully described in the discussion of electronic signature laws provided by DTC below, DTC proposes to apply New York law for this purpose, but also proposes to design the E–CD program such that E–CDs issued into DTC would be valid under the laws of all states that allow the use of electronic records and signatures in any transaction that would otherwise require a paper document and/or wet-ink signature.

Discussion of Electronic Signature Laws

The New York Electronic Signatures and Records Act

The New York Electronic Signatures and Records Act[24] (''ESRA'') governs the validity of electronic records and signatures in New York. ESRA is like UETA in that it accords the same power and effect to electronic records and signatures as would otherwise be accorded to writings under New York law.

ESRA does not apply to negotiable instruments, such as CDs, unless an electronic record of such instrument is created, stored or transferred in a manner that meets the Uniqueness Standard. If the Uniqueness Standard is met, then CDs that are issued, created and signed electronically have the same power and effect as paper CDs under New York law.

The Uniform Electronic Transactions Act

The Uniform Electronic Transactions Act[25] (''UETA''), has been adopted in various forms by 47 U.S. states.[26] UETA generally allows parties to agree to use electronic records and signatures in any transaction that would have otherwise required a paper document and/or wet-ink signature.

Section 16 of UETA[27] provides legal support for the creation, transferability and enforceability, of, among other things, negotiable instruments such as CDs, if they meet the following standards:

- The E–CD must be a ''transferable record,'' which is defined, in part, as an electronic record that would be a note under Article 3 of the UCC (CDs are notes in all relevant UETA jurisdictions), and the issuer has expressly agreed that it is a transferable record.
- The E–CD must initially be created as an electronic record, and not as a paper document that is converted to one.[28]
- Each E–CD must be stored in a system that meets the following standards (the ''*Section 16 Safe Harbor*''):
  - The E–CD is created, stored and assigned in a manner that a single authoritative copy of the transferable record exists which is unique, identifiable and, subject to certain exceptions, unalterable (the ''*Uniqueness Standard*'').
  - The authoritative copy must (i) identify the person claiming control (*i.e.,* the person to which the transferable record was issued or transferred), (ii) be maintained by the person claiming control or its designee and (iii) be unalterable except with the permission of the person claiming control.
  - Copies of and authorized revisions to the authoritative copy must be clearly marked as such.

DTC believes that any E–CD that is a transferable record and is stored in a system that falls within the Section 16

[18] *See* Rule 2, *supra* note 3.

[19] Unless otherwise specified, citations in this proposed rule change to provisions of the UCC are to the UCC as adopted in New York under the NYUCC.

[20] *See* NYUCC 3–102 and 3–104 (defining CDs as negotiable instruments).

[21] *See* NYUCC 8–102 (for NYUCC definitions of ''financial asset'' and ''security'').

[22] See NYUCC 8–501–8–508.

[23] *See* Comment 2 to Section 8–110 of the UCC (explaining that the law of the issuer's jurisdiction governs the validity of a security in order to ensure that a single body of law governs the questions addressed in Part 2 of Article 8). Part 2 of Article 8 of the UCC describes the circumstances in which an issuer can and cannot assert invalidity as a defense against purchasers, including lack of genuineness, unauthorized signatures and incomplete certificates. This implies that the term ''validity'' in Section 8–110 of the UCC refers to a broader set of issues than just the validity of issuance of the security under the issuer's governing documents and local law.

[24] N.Y. State Tech. Law § 30[•] (McKinney 2012).

[25] Unif. Electronic Transactions Act (Unif. L. Comm'n 1999).

[26] Illinois, New York and Washington have not adopted UETA. Although it has adopted UETA, California has not adopted Section 16 of UETA, which, as described in further detail below, is the section of UETA that provides for the electronic creation, signature and storage of negotiable instruments such as CDs.

[27] Unif. Elec. Transactions Act § 16 (Unif. L. Comm'n 1999).

[28] *See* Comment 2 to Section 16 of UETA (explaining that Section 16 is not intended to cover the conversion of a paper note to an electronic record; instead, transferable records must be electronic at the time they are created).

Safe Harbor will have the same rights and obligations of an equivalent writing under the UCC.[29]

Because the Section 16 UETA provisions are more robust than ESRA and the guidance in Section 16 of UETA is more developed, the E–CDs that would be made eligible by DTC would be structured to meet the requirements of UETA, including the Section 16 Safe Harbor, even though, as discussed below, the E–CDs will also be structured so that they are governed by New York law (including ESRA).[30] This construct will help ensure that an E–CD also will remain valid in the jurisdictions that have adopted Section 16 of UETA, in the unlikely event that a court of competent jurisdiction would determine not to recognize the selection of New York law.

E-Sign

The federal Electronic Signatures in Global and National Commerce Act[31] (''*E-Sign*'') generally provides for the legal effect, validity and enforceability of electronic signatures and records relating to transactions in interstate or foreign commerce and preempts state law with respect to such transactions except to the extent the state has enacted UETA or other alternative procedures or requirements that are consistent with E-Sign. E-Sign generally tracks the provisions of UETA but *does not apply to transactions that are governed by the UCC, such as the issuance of CDs.* E-Sign's equivalent of Section 16 of UETA expressly limits the use of transferable records to debt obligations secured by an interest in real property (*i.e.,* mortgage notes). Instead, state law must provide for the electronic creation and signature of a CD for it to be valid.

Others

In addition to New York, Illinois and Washington also did not adopt UETA. Illinois adopted an electronic records and signatures law that is similar to UETA and contains a section that is analogous to Section 16 of UETA. Washington adopted an electronic records and signatures law that is very different than UETA and does not clearly contemplate or provide for the issuance of electronic negotiable instruments such as CDs. As noted above, California has not adopted Section 16 of UETA. Therefore DTC is unable to conclude whether CDs that are created, signed and stored electronically would be valid under Washington or California law because it has not identified a legal framework under those laws whereby an issuer could issue a valid E–CD that could in turn be Deposited at DTC in accordance with the proposed rule change.

Proposed Rule Changes

Pursuant to the proposed rule change, DTC would amend the OA and Underwriting Service Guide, and create a new BLOR and the System E–CD Templates to be used exclusively for the issuance of E–CDs, in order to implement the proposed UWC system and E-vault for the issuance Delivery and Deposit of E–CDs and put in place the Procedures and a framework that conforms to the legal requirements for the maintenance of valid E–CDs, as described above.

Each Issuer that Opts to Participate in the E–CD Program Would Sign a New BLOR.

Pursuant to the proposed rule change, the OA would require each E–CD issuer to submit a new BLOR (''E–CD BLOR'') to DTC through UWC prior to its first issuance of E–CDs. In order to minimize the additional provisions in the Electronic Master Certificate (as defined below), the E–CD BLOR would contain supplemental terms related to the E–CD program (in addition to the representations that are currently included in a BLOR). The new E–CD BLOR would provide that all E–CDs issued in connection therewith and under one of the base CUSIP numbers set forth on the face of the E–CD BLOR would be part of the same transaction in which the E–CD BLOR was executed.[32]

Pursuant to Section 3–119 of the UCC, a holder in due course of a negotiable instrument must have notice of any separate agreement in order to be subject to its limitations. Therefore, the Electronic Master Certificate (as defined below) would contain a reference to the new E–CD BLOR.[33]

Each Issuer Issuing E–CDs Would Electronically Sign and Issue an Electronic Master Certificate.

E–CDs would be issued on a new form of master electronic certificate (''Electronic Master Certificate'') that has been specially created for the E–CD program. A separate electronic Master Certificate would be issued by the issuer for each broker that participates in an E–CD offering. Because E–CDs must necessarily be created, signed and thereafter maintained in electronic form using a system that complies with the Section 16 Safe Harbor, including the Uniqueness Standard, DTC would only make eligible E–CDs that have been initiated by the related broker/dealer through UWC, then created, signed and submitted to DTC through an electronic signature system designed by DTC for this purpose. UWC would allow Participants to initiate a new E–CD issuance by creating a draft Electronic Master Certificate using the applicable System E–CD Template that would be sent to an issuer for verification and signature. The issuer will verify and affix its electronic signature to the Electronic Master Certificate created by the Participant in a manner that creates an executed Electronic Master Certificate that complies with the Uniqueness Standard.

Once Issued, Each Original Electronic Master Certificate Would be Automatically Stored in an Electronic Vault Repository.

Once an issuer verifies and affixes its electronic signature to an Electronic Master Certificate, the Electronic Master Certificate would be automatically stored in an E-vault repository that complies with the Section 16 Safe Harbor, and the Electronic Master Certificate would immediately be deemed ''Delivered'' to DTC. The E-vault will identify Cede & Co. as the person to which the Electronic Master Certificate was issued. The E-vault will maintain an audit trail that will track all events that occur with respect to the Electronic Master Certificate, including any authorized changes, such as notations to reflect withdrawals, which will be noted in the audit trail instead of on the body of the Electronic Master Certificate. The audit trail will be incorporated as part of the Electronic

[29] Because Section 16 of UETA only contemplates a transferable record that has been electronic since its creation and requires that the transferable record comply with the Section 16 Safe Harbor, including the Uniqueness Standard, at all times, DTC believes that the legal issues relating to the electronic signature of a negotiable instrument such as a CD are necessarily intertwined with its electronic creation and storage. Thus, an electronic negotiable instrument cannot be created outside of an appropriate system that complies with the Section 16 Safe Harbor even if electronically signed.

[30] Although Section 307 of ESRA does not provide the same robust provisions and commentary as Section 16 of UETA, it is still sufficiently clear that E–CDs that meet the Uniqueness Standard are valid.

[31] Electronic Signatures in Global and National Commerce 15 U.S.C. § 70[•].

[32] Section 3–119 of the NYUCC provides that a negotiable instrument may be ''modified or affected by any other written agreement executed as part of the same transaction.''

[33] While a CD cannot expressly be made subject to the terms of an additional agreement, Section 3–105(1)(c) of the UCC permits the CD to refer to or state that it arises out of a separate agreement.

Master Certificate in accordance with the BLOR.

E–CDs Would be Governed by New York Law.

The parties would select New York law as the governing law for all E–CDs, as described below. Because there are variations between the electronic record and signature laws (including in the provisions of UETA, as adopted) across the various U.S. jurisdictions, the selection of New York law (including ESRA) as the law governing the E–CDs would allow DTC to structure a single E–CD program that will be valid for issuers in all U.S. jurisdictions.

DTC believes that the System E–CD Templates for the E–CDs and the proposed BLOR to be used for E–CD issuances have been structured in a manner that complies with the applicable rules governing jurisdiction selection, as follows:

- Each BLOR would provide that the laws of New York would govern the terms of the E–CD, which is issued and payable to DTC in New York. The jurisdiction selection rule in Section 1–301 of the UCC, which applies to CD issuances under Article 3 of the UCC, allows parties to a transaction that bears a reasonable relation to a state to select the laws of that state to govern their rights and duties.
- Each Electronic Master Certificate would have a minimum denomination of $250,000. The jurisdiction selection rule in Section 5–1401 of the New York General Obligations Law allows parties to any transaction that results in an obligation of at least $250,000 to select New York law to govern their rights and obligations.
- Each Electronic Master Certificate would expressly provide that it is payable in New York. The general rule in New York (and in most other jurisdictions) is that a note (such as a CD) that is executed in one state and payable in another, is governed as to its nature, validity, interpretation and effect by the laws of the state where it is made payable.

E–CDs Would be Structured as ''financial assets''—but not as ''Securities''—Under Article 8 of the UCC.

Section 8–110 of the UCC provides that only the law of the issuer's jurisdiction will govern the ''validity'' of a ''security''—the laws of another jurisdiction cannot be selected to govern validity issues. The term ''validity'' is not defined in the UCC. DTC believes that laws governing the creation and existence of an electronic record as a substitute for a written instrument may be viewed as laws that govern the ''validity'' of an instrument.[34]

CDs may be both ''negotiable instruments'' under Article 3 of the UCC and ''securities'' under Article 8 of the UCC, in which case the provisions of Article 8 will govern the CD.[35] This means that an E–CD that is both a negotiable instrument and a security, will be governed as to its validity by the law of the issuer's jurisdiction, by virtue of Section 8–110 of the UCC. If the validity of a security is determined to include its electronic nature, then the electronic signature and record laws of each individual issuer's jurisdiction would apply to each E–CD, and the selection of New York's ESRA would not be valid. As a result, any jurisdiction that has not enacted a law that clearly provides for electronic negotiable records would necessarily have to be excluded from the E–CD program.[36]

In order to ensure that the parties can properly choose New York law, including ESRA, to govern the E–CDs, E–CDs would be structured so that they are not Article 8 Securities. To do this, each Electronic Master Certificate would provide that it can be transferred only by delivery and indorsement. A ''security,'' as defined in Section 8–102(a)(15) of the UCC, must be in ''bearer'' or ''registered'' form. ''Bearer form'' requires that the security be payable to bearer. Because each Electronic Master Certificate would be payable to Cede & Co., as nominee for DTC, it would not be in bearer form. ''Registered form'' requires that transfers of a security be registered upon books maintained for that purpose by or on behalf of the issuer, or the security certificate must so state. Because E–CDs would be transferrable only by delivery and indorsement and not on the books of the issuer, they will not be in registered form and therefore will not fall within the definition of ''security'' in Article 8 of the UCC.

Although the E–CDs would not be Article 8 securities, under Section 8–103(d) of the UCC they will still be ''financial assets'' if held in a securities account.[37] DTC Rule 6 provides, among other things, that DTC will accept Securities for deposit and may offer such other services as are consistent with its purposes and powers.[38] ''Securities'' are defined in the DTC Rules as anything that would be a ''financial asset'' under Section 8–102 of the UCC. The DTC Rules further provide that any item credited to a securities account will be deemed a Security under the DTC Rules and treated as a financial asset under Article 8 of the UCC. Accordingly, E–CDs, each of which will be a financial asset under Article 8 of the UCC, may be made eligible by DTC, credited by DTC to the securities accounts of its participants, and treated as a ''Security'' for all purposes, in each case under the DTC Rules.

The rules relating to the indirect holding system, security entitlements and the rights and duties of securities intermediaries (*e.g.,* DTC) and entitlement holders, which are specified in Part 5 of Article 8 of the UCC, apply to all financial assets.[39] Thus, although

[34] *See* Comment 2 to Section 8–110 of the UCC (explaining that the law of the issuer's jurisdiction governs the validity of a security in order to ensure that a single body of law governs the questions addressed in Part 2 of Article 8). Part 2 of Article 8 of the UCC describes the circumstances in which an issuer can and cannot assert invalidity as a defense against purchasers, including lack of genuineness, unauthorized signatures and incomplete certificates. This implies that the term ''validity'' in Section 8–110 of the UCC refers to a broader set of issues than just the validity of issuance of the security under the issuer's governing documents and local law.

[35] *See* Section 3–103(1) of the UCC (providing that Article 3 does not apply to investment securities); Comment 2 to Section 3–103 of the UCC (explaining that if an instrument is negotiable in form under Article 3, but is, because of its manner of use, a ''security'' under Article 8, Article 8 and not Article 3 applies); and Section 8–103(d) of the UCC and Comment 5 to Section 8–103 of the UCC (providing that a writing that is a security certificate is governed by Article 8, even though it also meets the requirements of Article 3).

[36] In particular, as noted above, if the E–CDs are Article 8 securities, then DTC would be unable to conclude that E–CDs would be valid under the laws of California and Washington, and issuers in California and Washington would likely be excluded from the E–CD program.

[37] Section 8–103(d) of the UCC provides, in part, ''a negotiable instrument governed by Article 3 is a financial asset if it is held in a securities account.'' *See also,* the definition of ''financial asset'' in Section 8–102(a)(9) of the UCC, which provides that any property held by a securities intermediary for another person in a securities account will be a financial asset if the securities intermediary has expressly agreed with the other person that the property is to be treated as such.

[38] DTC's corporate powers are listed in its Organization Certificate, which include, among other things, the receipt on deposit for safe-keeping money, securities, papers of any kind and any other personal property for the account of its participants in connection with DTC's acting as a clearing corporation.

[39] *See* Comment 5 to Section 8–103 of the UCC (explaining that the indirect holding rules apply to any Article 3 negotiable instrument that is held through a securities intermediary; Comment 9 to Section 8–102 of the UCC (explaining that the indirect holding rules in Part 5 of Article 8 may apply to financial assets even where the rules in Parts 2, 3 and 4 of Article 8 do not apply); and Comment 1 to Section 8–104 of the UCC (explaining that Article 3 and not Article 8 specifies how one acquires a direct interest in a bankers' acceptance, which is a negotiable instrument under Article 3 and a financial asset under Article 8, and Part 5 of Article 8 governs the rights of a clearing corporation's participants with respect to a bankers' acceptance that is held by the clearing corporation on account for its participants).

the E–CDs would not be securities, because they would be financial assets, they may be issued and deposited with DTC, and DTC can credit security entitlements therein to its Participants, as it currently does with respect to paper CDs.[40] E–CDs would be maintained as fungible bulk by DTC, in accordance with the requirement in Section 8–504 of the UCC that a securities intermediary maintain a financial asset in a quantity corresponding to the aggregate of all security entitlements it has established therein.[41]

Summary of Selected E–CD Terms

Section 3–104 of the UCC provides that a negotiable instrument may only contain an unconditional promise to pay a sum certain, a prescribed set of other obligations and powers, and no other promise, order, obligation or power. Because it is unclear exactly what would constitute an additional obligation or power, only those provisions that are necessary to ensure that a holder can ascertain all of the E–CDs essential terms[42] would be included in the Electronic Master Certificate, either directly, or by reference to the issuer's E–CD BLOR.

Selected Terms Contained in the Master Electronic Certificate

The following terms would be included in each System E–CD Template:

- The E–CD would be payable in New York—this ensures that the E–CD will be governed by New York law.
- The E–CD is issued in connection with a BLOR between the issuer and DTC—this allows for the additional terms contained in the BLOR to modify or affect the terms of the E–CD and puts any holder of the E–CD on notice of the existence of such additional terms.
- The E–CD is an electronic record created in accordance with ESRA, and a transferable record under UETA—this makes clear the issuer's intent that the E–CD be a valid electronic instrument under both ESRA and UETA.[43]
- The E–CD would be stored in the E-vault—this is necessary to understand how the notation and transfer provisions in the Electronic Master Certificate will work.
- The E–CD may be transferred only by delivery and indorsement—this ensures that the E–CD would not be an Article 8 security and, therefore, not subject to the limitation on jurisdiction selection with respect to validity.

Selected Terms Contained in the BLOR:

- Paper out provision—this allows DTC to convert the E–CD to a paper CD, if deemed necessary, without further action from the issuer.
- Selection of New York governing law and jurisdiction—included in the BLOR to minimize additions to the Electronic Master Certificate.
- No contravention representation by the issuer—the issuer is responsible for ensuring that the issuance of an E–CD complies with applicable local law and regulation and the issuer's governing documents.

Other Proposed Changes to the OA

In addition to the proposed changes described above, the OA would be amended as follows:

a. Section I.A.1. would be amended to add a reference to UWC, in addition to UW SOURCE, as a system that may be used by Participants to submit eligibility requests. Additionally, the hyperlink to the website of DTC's parent, The Depository Trust & Clearing Corporation (''DTCC'') for information on UW SOURCE will be amended to refer to the Underwriting section of DTCC's website. The proposed changes in this section would facilitate Participants' ability to access DTC's systems for eligibility requests.

b. Section 1.B.1 relating to the documentation requirements for BEO Securities would be amended to add a new subsection c. with the following text under a new heading titled ''Electronic Certificates for Retail CDs'':

Issuers leveraging the use of electronic master certificates for Retail CDs must submit to DTC on DTC's form, a fully executed BLOR and its associated Rider, for each base CUSIP issuing Retail CDs through the electronic process. For the current form of the E–CD BLOR please refer to *https://www.dtcc.com/legal/issue-eligibility.*

In addition, subsection a. of this Section, which describes the current Letter of Representation requirements for BEO Securities, would be amended in order to clarify that the requirements described in that subsection apply to BEO Securities other than E–CDs, namely FAST securities or securities where a physical master certificate is delivered to DTC.

The proposed changes to this section would facilitate Participants' and issuers' access to documentation used in connection with eligibility requests.

c. Section 1.C.1., which relates to considerations relating to eligibility of CDs, would be amended to add a subsection c. that would be titled ''Electronic Master Certificates,'' to provide for issuance and Delivery of E–CDs and a legal disclaimer as follows:

In lieu of issuing and delivering physical master certificates to DTC, the Underwriter can facilitate issuance of Retail CDs for state and federally chartered banks in electronic form by using specific master certificate templates (''System E–CD Templates'') provided by DTC through UWC.

The relevant data (*e.g.,* maturity date) will be populated into a System E–CD Template as entered by the Underwriter into the UWC application. It is the responsibility of the Underwriter to disseminate the populated electronic master certificate to the Issuer for electronic signature via UWC. The Issuer must electronically sign the electronic master certificate prior to closing.

Each electronic master certificate is stored in a secure electronic vault maintained by DTC.

For Retail CDs that do not conform to the System E–CD Templates, a physical master certificate must be delivered to DTC prior to closing.

Note: Whether issued in electronic or physical form, securities should be delivered to DTC by no later than noon ET on the business day prior to the Closing Date as outlined in Exhibit B.

IMPORTANT LEGAL NOTICE:

DTC DOES NOT VALIDATE, CERTIFY, REPRESENT OR SEEK TO CONFIRM (i) THE VALIDITY OF THE DATA ELEMENTS ENTERED BY A PARTICIPANT, ITS CORRESPONDENT UNDERWRITERS AND OR VENDORS INTO UWC (TOGETHER WITH ANY OTHER PERSON USING UWC, ''UWC USERS'') OR (ii) THE FITNESS OF THE ELECTRONIC MASTER CERTIFICATES FOR ANY PURPOSE. USE OF UWC AND/OR ELECTRONIC MASTER CERTIFICATES BY ANY UWC USER SHALL BE DEEMED TO CONSTITUTE A WAIVER OF ANY AND ALL CLAIMS (WHETHER DIRECT OR INDIRECT) AGAINST DTC AND ITS AFFILIATES, AND AN AGREEMENT THAT DTC

[40] DTC currently accepts for deposit bankers' acceptances, which are not Article 8 securities, and proposes to do the same with respect to the E–CDs.

[41] Comment 1 to Section 8–504 of the UCC explains that Section 8–504 recognizes the reality that these items are held as fungible bulk and are not identified to a customer. The language in Section 8–504 of the UCC applies to all financial assets (not just securities) and would therefore provide the basis for holding E–CDs as fungible bulk, even if they are not Article 8 securities.

[42] *See* Comment 8 to Section 3–105 of the UCC (''an instrument is not negotiable unless the holder can ascertain all of its essential terms from its face'').

[43] Section 16 of UETA requires that the issuer expressly agree that the E–CD is a transferable record. Comment 2 to Section 16 of UETA explains that it is likely that this agreement will be set forth in the body of the electronic record.

AND ITS AFFILIATES SHALL NOT BE LIABLE FOR ANY LOSS, COST, EXPENSE OR LIABILITY IN RELATION TO THE USE OF UWC AND/OR DISSEMINATION OR USE OF RELATED DOCUMENTATION, INCLUDING MASTER CERTIFICATES OF DEPOSIT, WHICH ARE PROVIDED ''AS IS.''

EACH PARTICIPANT AGREES TO INDEMNIFY AND HOLD HARMLESS DTC AND ITS AFFILIATES FROM AND AGAINST ANY AND ALL LOSSES, DAMAGES, COSTS, JUDGMENTS, CHARGES AND EXPENSES ARISING OUT OF OR RELATING TO ANY USE OF UWC BY THE PARTICIPANT AND/OR ANY UWC USER, INCLUDING BUT NOT LIMITED TO ANY ISSUANCES OF CERTIFICATES OF DEPOSIT AND RELATED TRANSACTIONS BY SUCH PERSON OR ITS AFFILIATES, AGENTS, CUSTOMERS OR DESIGNEES.''

This proposed change would facilitate the implementation and use of System E–CD Templates, as described above, and set forth a disclaimer by DTC and indemnification consistent with the requirements of DTC's current Rule and Procedures which allocate the responsibility to Participants for the accuracy of information and instructions provided by them to DTC and the indemnification of DTC by Participants in this regard.[44]

d. Exhibit B, which sets forth timeframes for submission of documents by Participants to DTC Underwriting in connection with eligibility requests, would be revised to reflect that the timeframes described in the exhibit relate to documents and information submitted through UWC, in addition to UW SOURCE. The proposed change to Exhibit B would align timeframes for submissions through UWC with those that apply to submissions to UWSOURCE.

e. Technical changes with respect to spelling, punctuation and spacing of text would also be made. The proposed technical changes to the OA would provide enhanced clarity for Participants and Issuers with respect to Procedures relating to eligibility processing and the Deposit of CDs.

Proposed Changes to the Underwriting Service Guide

a. A glossary description provided for BLOR in the Underwriting Guide currently describes a BLOR as an agreement between DTC and an issuer of municipal securities. As described above, a BLOR or LOR is required to be submitted with respect to any issue of BEO Securities which also includes corporate Securities. Pursuant to the proposed rule change, the text would be clarified so that the description of the term BLOR is not described as limited to applying only to municipal Securities. The proposed change to this glossary description would provide enhanced clarity for Participants and Issuers with respect to Procedures relating to eligibility documentation required for BEO Securities.

b. Pursuant to the proposed rule change, DTC would eliminate references to the Participant Terminal System (''PTS'') functions ART and PUND as these functions have become obsolete. ART related to inquiries about transactions of a Participant processed by DTC and PUND related to inquiries relating to issues and certificates for issues held by a Participant. Participant inquiries may now be directed to the Client Center available on dtcc.com.[45] The proposed rule change would update the Underwriting Service Guide to provide clarity for Participants on how to submit inquires relating to DTC's services.[46]

c. Pursuant to the proposed rule change, a reference to the IMPP function in PTS would be deleted. The IMPP function allowed Participants to view Important Notices about underwriting, transfer agents, and money market instruments (''MMI''). This function is not being widely used by Participants. All DTC Important Notices are accessible on dtcc.com.[47]

d. The Section titled ''Packaging Inquiries'' provides information and requirements relating to the delivery of securities to DTC. Pursuant to the proposed rule change, DTC would add the following text under a subheading titled ''Retail (brokered) Certificates of Deposit'' to note the existence of the proposed process for E–CDs with a reference to the OA for additional information:

In lieu of issuing and delivering physical master certificates to DTC, the Underwriter can facilitate issuance of Retail CDs for state and federally chartered banks in electronic form by using available master certificate templates through the Underwriting Central system (''UWC''), in accordance with the provisions of the OA.

Each electronic master certificate deposited at DTC is stored in a secure electronic vault maintained by DTC.''

This Section would also include use, waiver of liability and indemnification provisions as follows:

IMPORTANT LEGAL NOTE:

DTC DOES NOT VALIDATE, CERTIFY, REPRESENT OR SEEK TO CONFIRM (i) THE VALIDITY OF THE DATA ELEMENTS ENTERED BY A PARTICIPANT, ITS CORRESPONDENT UNDERWRITERS AND OR VENDORS INTO UWC (TOGETHER WITH ANY OTHER PERSON USING UWC, ''UWC USERS'') OR (ii) THE FITNESS OF THE ELECTRONIC MASTER CERTIFICATES FOR ANY PURPOSE. USE OF UWC AND/OR ELECTRONIC MASTER CERTIFICATES BY ANY UWC USER SHALL BE DEEMED TO CONSTITUTE A WAIVER OF ANY AND ALL CLAIMS (WHETHER DIRECT OR INDIRECT) AGAINST DTC AND ITS AFFILIATES, AND AN AGREEMENT THAT DTC AND ITS AFFILIATES SHALL NOT BE LIABLE FOR ANY LOSS, COST, EXPENSE OR LIABILITY IN RELATION TO THE USE OF UWC AND/OR DISSEMINATION OR USE OF RELATED DOCUMENTATION, INCLUDING MASTER CERTIFICATES OF DEPOSIT, WHICH ARE PROVIDED ''AS IS.''

EACH PARTICIPANT AGREES TO INDEMNIFY AND HOLD HARMLESS DTC AND ITS AFFILIATES FROM AND AGAINST ANY AND ALL LOSSES, DAMAGES, COSTS, JUDGMENTS, CHARGES AND EXPENSES ARISING OUT OF OR RELATING TO ANY USE OF UWC BY THE PARTICIPANT AND/OR ANY UWC USER, INCLUDING BUT NOT LIMITED TO ANY ISSUANCES OF CERTIFICATES OF DEPOSIT AND RELATED TRANSACTIONS BY SUCH PERSON OR ITS AFFILIATES, AGENTS, CUSTOMERS OR DESIGNEES.

The proposed changes to this section would facilitate the implementation and use of System E–CD Templates, as described above, and set forth a disclaimer by DTC and indemnification consistent with the requirements of DTC's current Rule and Procedures which allocate the responsibility to Participants for the accuracy of information and instructions provided by them to DTC and the indemnification of DTC by Participants in this regard.[48]

System Access and Information Security Considerations

A Participant controls access to its account and transaction information relating to its holdings and activity in DTC's systems through DTCC's access

[44] *See* OA, *supra* note 3 at ii-iii and Rule 6, *supra* note 3.

[45] *See* Securities Exchange Act Release No. 88050 (January 27, 2020), 85 FR 5728 (January 31, 2020) (File No. SR–DTC–2020–002).

[46] *Id.*

[47] *See https://www.dtcc.com/legal/important-notices.*

[48] *See* Underwriting Service Guide at 2–3, *supra* note 3 at ii–iii and Rule 6, *supra* note 3.

coordinator program.[49] This program includes, but is not limited to, controls on access to UWSOURCE, and would also encompass UWC access upon implementation of the proposal. DTC may provide to the issuer of any security, including but not limited to CDs, at any time credited to the Account of a Participant the name of the Participant and the amount of the issuer's securities so credited, and the Corporation is authorized to provide similar information to any appropriate governmental authority.[50] An issuer must provide authorization annually for a third party agent to obtain access to an position information with respect to Securities of such issuer.[51]

DTCC, for itself and on behalf of its subsidiaries, including DTC, maintains a privacy policy, which among other things, states that DTCC maintains an information security program setting forth standards for maintaining administrative, technical and physical safeguards to protect the personal information provided by users of services, which would include personal information provided through the E–CD program, against accidental, unlawful or unauthorized destruction, loss, alteration, access, disclosure or use. DTCC periodically tests the security protections of its information systems and monitors the effectiveness of its information security controls, systems and procedures.[52]

Implementation Timeframes

The proposed rule change would be implemented by DTC in two phases, with the first phase beginning after approval of the proposed rule change by the Commission and prior to the end of January 2021.

Initially, underwriters would be invited to participate, on a voluntary basis. The underwriters that would participate in this initial phase are those that expressed interest in participating after outreach by DTC to those Participants that participated in the development of the proposed E–CD program. The Participants that would participate during the first phase are those Participants that expect to be able to submit an issuance during this phase that would meet the requirements of the proposed E–CD program, as those requirements are described above. This phased approach to implementation would facilitate a smooth transition, from an operational perspective, for ultimately making UWC available for all E–CD offerings of state and federally chartered banks that conform to the System Templates.

Subsequently, the E–CD program would be made available to all underwriters in early 2021, with the implementation date of such availability to be announced via Important Notice. Upon approval of the proposed rule change, a legend would be added to the OA and Underwriting Service Guide indicating that the applicable provisions relating to E–CDs would apply only to (i) issuers whose issuances are submitted to DTC through UWC and (ii) Participants that submit and/or hold eligible issuances submitted through UWC, during this first phase, until a date to be announced by DTC via Important Notice when the E–CD program would become available, on a voluntary basis, for all eligible issuances. This legend would read as follows:

Applicable provisions relating to UWC and Electronic Master Certificates for Certificates of Deposit, as described herein, apply only to (i) Issuers whose issuances are submitted to DTC through UWC, and (ii) Participants that submit and/or hold eligible issuances submitted through UWC during an initial phase of the electronic CD program, until a date to be announced by DTC via Important Notice when the E–CD program would become available, on a voluntary basis, for all eligible issuances of state and federally chartered banks. This legend will be removed upon full implementation of the E–CD program on a date to be announced via Important Notice.

Issuers and underwriters that choose not to use the new E–CD program could continue to use the existing process through UW SOURCE, including making Deposits using physical certificates.

2. Statutory Basis

Section 17A(b)(3(F) of the Act

The Clearing Agencies believe that the Framework is consistent with Section 17A(b)(3)(F) of the Act,[53] for the reasons described below.

Section 17A(b)(3)(F) of the Act[54] requires, *inter alia,* that the rules of a clearing agency be designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible. As described above, the proposed rule change would provide for the issuance of Electronic Master Certificates for E–CDs which would be stored in a secure E-Vault, as described above. Therefore, by providing for the storage of E–CDs in a secure electronic vault, the proposed rule change is designed to assure the safeguarding of securities which are in the custody or control of DTC.

Section 17A(b)(3)(F) of the Act also requires that the rules of the clearing agency be designed, *inter alia,* to promote the prompt and accurate clearance and settlement of securities transactions. DTC believes that the proposed rule change is consistent with this provision of the Act because DTC believes that the proposed E–CD program would reduce closing delays caused by disruptions to physical delivery of certificates by eliminating the need for DTC to receive original paper master certificates in advance of CD issuances that would be eligible for issuance through the new program. Therefore, by facilitating the potential reduction of closing delays for issuances of CDs that utilize the E–CD program, DTC believes that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions.

DTC also believes that the proposed rule changes are consistent with Section 17A(b)(3)(F), cited above, because by making technical changes with respect to spelling, punctuation and spacing of text within the Procedures, as described above, the proposed rule change would provide enhanced clarity for Participants and Issuers with respect to Procedures relating to eligibility processing and the Deposit of CDs. By providing Participants and Issuers with enhanced clarity with regard to the Procedures relating to, and therefore facilitating eligibility processing and the Deposit of CDs that may be the subject of transactions processed through the DTC system, DTC believes that the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions consistent with the Act.

Rule 17Ad–22(e)(1)

Rule 17Ad–22(d)(1) promulgated under the Act[55] requires that each registered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for a well-founded, clear, transparent, and enforceable legal basis for each aspect of its activities in all relevant jurisdictions. As described above, DTC believes that requiring E–CDs at DTC to be negotiable instruments governed by New York law would allow for the valid issuance into

[49] *https://www.dtcc.com/client-center/access-coordinators.*

[50] *See* Rule 2, *supra* note 3.

[51] *See* OA, *supra* note 3 at 55.

[52] *See* Privacy Policy on DTCC website, *available at https://www.dtcc.com/privacy.*

[53] 15 U.S.C. 78q–1(b)(3)(F).

[54] *Id.*

[55] 17 CFR 240.1717Ad–22(d)(1).

DTC of E–CDs of issuers in all relevant jurisdictions. Therefore, by providing for E–CDs to be deemed negotiable instruments governed by New York law, as described above, DTC believes that DTC's Rules and Procedures, as amended by the proposed rule change, would provide for a well-founded, clear, transparent, and enforceable legal basis for the valid issuance of E–CDs into DTC from issuers domiciled in any relevant jurisdiction.

Also, as described above, because DTC believes the Section 16 UETA provisions are more robust than ESRA and the guidance in Section 16 of UETA is more developed, the proposal provides would provide that E–CDs that would be made eligible by DTC would be structured to meet the requirements of UETA, including the Section 16 Safe Harbor, even though, as discussed above, the E–CDs would also be structured so that they are governed by New York law (including ESRA).[56] DTC believes that this construct will help ensure that an E–CD also would be valid in the jurisdictions that have adopted Section 16 of UETA, in the unlikely event that a court of competent jurisdiction would determine not to recognize the selection of New York law. Therefore, DTC believes that structuring E–CDs to meet the requirements of UETA would allow DTC's Rules and Procedures to provide additional support for a well-founded, clear, transparent, and enforceable legal basis for the valid issuance of E–CDs into DTC from issuers domiciled in jurisdictions that have adopted Section 16 of UETA.

DTC believes that with respect to all jurisdictions, including those that have not adopted Section 16 of UETA or ESRA, the Procedures, as amended pursuant to the proposed rule change, would continue to facilitate the issuance of CDs in physical form into DTC. As indicated above, the validity of a physical security does not depend on the provisions of electronic signature laws. DTC believes that Article 8 of the UCC as adopted in all relevant jurisdictions allows for the physical issuance of CDs as securities. Therefore, an issuer from any relevant jurisdiction would continue to be able to issue valid CDs in physical form that meet DTC's eligibility requirements into DTC. Therefore, DTC believes that DTC's Procedures, as amended pursuant to the proposed rule change, would continue to provide a well-founded, clear, transparent, and enforceable legal basis for the valid issuance of CDs into DTC from issuers domiciled in any relevant jurisdiction.

Rule 17Ad–22(e)(10)

Rule 17Ad–22(d)(10) promulgated under the Act[57] requires that each registered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed, *inter alia,* to, as applicable, establish and maintain operational practices that manage the risks associated with such physical deliveries. As mentioned above, the proposed rule change would eliminate the requirement for the delivery of a physical master certificate for a CD offering to the extent it is eligible for, and processed through, the electronic process established through UWC, and stored in the E-Vault. DTC believes the proposed electronic process for Delivery of E–CDs to DTC would reduce risks of loss related to the physical CDs that would otherwise be physically transported to DTC for Deposit and later returned to issuers or their agents for redemption upon maturity of the CD. Therefore, by reducing the risk of loss of physical master certificates by allowing their replacement with Electronic Master Certificates, DTC believes that the proposed rule change would establish and maintain operational practices that manage risks associated with eligible offerings of CDs, as described above.

Rule 17Ad–22(e)(11)

Rule 17Ad–22(e)(11) promulgated under the Act[58] requires that each covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable, when the covered clearing agency provides central securities depository services: (i) Maintain securities in an immobilized or dematerialized form for their transfer by book entry, ensure the integrity of securities issues, and minimize and manage the risks associated with the safekeeping and transfer of securities; (ii), *inter alia,* prevent the unauthorized creation or deletion of securities; and (iii) Protect assets against custody risk through appropriate rules and procedures consistent with relevant laws, rules, and regulations in jurisdictions where it operates.

DTC believes the proposed rule change is consistent with the provisions of Rule 17Ad–22(e)(11)(i), cited above, because (i) by providing for the Deposit of Securities in the name of Cede & Co. to be deposited in electronic form and stored in an electronic vault, the proposed rule change would provide for the immobilization and dematerialization of master certificates for the transfer of CDs by book entry, (ii) the integrity of E–CDs would be maintained by such storage in the secure electronic vault and (iii) it would minimize the risks associated with the safekeeping and transfer of securities by providing for purely electronic processing of the certificates and therefore preventing potential of loss of certificates if the applicable issues were to be issued and processed in physical form.

DTC believes the proposed rule change is consistent with the provisions of Rule 17Ad–22(e)(11)(ii), cited above, because it would provide for a process allowing the issuance and Deposit of the related Securities through the use of UWC and associated System Templates for creation of E–CDs, signature of E–CDs and Delivery of the E–CDs to DTC for storage in the E-Vault. Through the use of this centralized process for issuance and processing of CDs, the proposed rule change would facilitate the prevention of the unauthorized creation or deletion of securities processed through the E–CD program.

DTC believes the proposed rule change is consistent with the provisions of Rule 17Ad–22(e)(11)(iii) because, as discussed above, it would provide for Procedures for the issuance of E–CDs, Deposit of E–CDs, and custody of E–CDs in the E-Vault in a manner consistent with the requirements applicable to the validity of electronic negotiable instruments under the NYUCC and the e-signature laws, as discussed above. The applicable Procedures would be established through proposed rule changes to the Underwriting Service Guide and the OA, and the utilization of Electronic Master Certificates in the forms of System E–CD Templates issued under the applicable E–CD BLOR, as discussed above. Therefore, DTC believes that E–CDs issued, Deposited and stored in accordance with the proposed rule change would be Financial Assets that constitute Eligible Securities under the Rules, and would be valid and binding negotiable instruments under applicable law, and therefore protect the applicable assets against custody risk through appropriate rules and procedures consistent with relevant laws, rules, and regulations in jurisdictions where DTC operates.

[56] Although Section 307 of ESRA does not provide the same robust provisions and commentary as Section 16 of UETA, it is still sufficiently clear that E–CDs that meet the Uniqueness Standard are valid.

[57] 17 CFR 240.1717Ad–22(d)(10).

[58] 17 CFR 240.1717Ad–22(d)(11)(i)(ii) and (iii).

(B) Clearing Agency's Statement on Burden on Competition

Once the proposed rule change is fully implemented as described above, DTC does not believe that the proposed rule change would have any impact, or impose any burden, on competition because the proposed rule change provides for an additional method under which Participants may request eligibility of, process, and Deliver CDs on a voluntary basis. The new method would be available to all Participants through UWC, on a date to be announced by Important Notice.

The existing method for Deposit of CDs at DTC, that includes the use of a physical master certificate, would continue to remain available to all Participants even after the new E–CD process was implemented.

DTC does not believe that the aspect of the proposed rule change to initially make the proposed E–CD process available to a subset of Participants prior to full implementation, as described above, would have any impact, or impose any burden on competition. Participants not participating in the initial phase described above would be able to continue to Deposit eligible CDs in physical form. However, to the extent the proposed rule change could cause a burden because certain Participants would continue to be able to Deliver electronic certificates during an interruption of Participants' ability to make physical delivery of securities to DTC, and/or DTC's ability to accept physical deliveries of securities, DTC does not believe the burden have a significant impact on competition because Participants could utilize the LOP process, mentioned above, to effect Delivery of a security represented in physical form to DTC despite any such interruption of physical delivery services.

DTC does not believe that the proposed rule change to make technical changes with respect to spelling, punctuation and spacing of text within the Procedures, as described above, would have any impact, or impose any burden, on competition because the technical changes would merely provide enhanced clarity with respect to the Procedures and not have an effect on the rights or obligations of Participants and/or Issuers with respect to eligibility processing and Deposit of Eligible Securities at DTC.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not solicited or received any written comments relating to this proposal. DTC will notify the Commission of any written comments received by the DTC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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–DTC–2020–017 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–DTC–2020–017. 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 DTC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–DTC–2020–017 and should be submitted on or before December 28, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[59]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26676 Filed 12–3–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90536; File No. SR–CBOE–2020–106]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Its Rules Regarding the Minimum Increments for Electronic Bids and Offers and Exercise Prices of Certain FLEX Options and Clarify in the Rules How the System Ranks FLEX Option Bids and Offers for Allocation Purposes

November 30, 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 November 16, Cboe Exchange, Inc. (''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change, and on November 30, 2020, the Exchange filed Amendment No. 1 to the proposed rule change, which amended and replaced the proposed rule change in its entirety. The proposed rule change, as modified by Amendment No. 1, as described in Items I, II, and III

[59] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its Rules regarding the minimum increment for electronic bids and offers, as well as the minimum increment for exercise prices, of certain FLEX Options [3] and clarify in the Rules how the System ranks FLEX Option bids and offers for allocation purposes (and make various other nonsubstantive, clarifying changes). This Amendment No. 1 replaces the initial rule filing in its entirety. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the minimum increment for bids and offers, as well as the minimum increment for exercise prices, of FLEX options submitted to an electronic FLEX auction and make conforming changes in other Rules. The Exchange also proposes to make various clarifying and nonsubstantive changes, including how the System ranks FLEX Option bids and offers for allocation purposes.

A FLEX Option [4] series is eligible for trading on the Exchange upon submission to the system of a FLEX Order [5] by a FLEX Trader (the ''Submitting FLEX Trader'') [6] for that series pursuant to Rules 5.72 through 5.74.[7] When submitting a FLEX Order into the system, the Submitting FLEX Trader must include the applicable terms of a FLEX Option series, including an exercise (or strike) price.[8] The exercise price of a FLEX Option may currently be expressed as either (1) a fixed price expressed in terms of dollars and decimals or a specific index value, as applicable (which may not be smaller than $0.01), or (2) a percentage of the closing value of the underlying equity security or index, as applicable, on the trade date (which may not be smaller than 0.01%).[9]

Pursuant to current Rule 5.4(c)(4)(B), the minimum increment for bids and offers on FLEX Options with (1) an exercise price expressed as a fixed price may not be smaller than $0.01 and (2) an exercise price expressed as a percentage of the closing value of the underlying equity security or index on the trade date may not be smaller than 0.01%.[10] The proposed rule change amends Rule 5.4(c)(4) to provide that:

(1) The minimum increment for bids and offers on a FLEX Options series if the exercise price is expressed as a fixed price may not be smaller than $0.001 (for FLEX Orders and auction responses submitted to an electronic FLEX Auction); and

(2) the minimum increment for bids and offers on a FLEX Options series if the exercise price is expressed as a percentage of the closing value of the underlying equity security or index on the trade date may not be smaller than 0.0001% (for FLEX Orders and auction responses submitted to an electronic FLEX Auction).[11]

Similarly, the proposed rule change amends Rule 4.21(b)(6)(A) to provide that:

(1) An exercise price expressed as a fixed price may not be in increments smaller than $0.001 (for FLEX Orders submitted to an electronic FLEX Auction); and

(2) an exercise price expressed as a percentage of the closing value of the underlying equity security or index, as applicable, on the trade date may not be in increments smaller than 0.0001% (for FLEX Orders submitted to an electronic FLEX Auction).[12]

The Exchange believes there is a demand from customers for this additional precision regarding the exercise prices and premiums for FLEX Options series that are submitted into electronic FLEX Auctions. This additional level of precision will provide investors with additional flexibility regarding the prices at which they may execute and exercise their FLEX Options on the Exchange, as investors may execute and exercise over-the-counter options with similar precisions.

Current Rule 4.21(b)(6) defines the permissible exercise prices for FLEX Options by referencing the minimum increments for bids and offers set forth in Rule 5.4. Specifically, the current rule states the exercise price (which the

[3] The term ''FLEX Option'' means a flexible exchange option. *See* Rule 1.1.

[4] A ''FLEX Option'' is a flexible exchange option. *See* Rule 1.1.

[5] A ''FLEX Order'' is an order submitted in a FLEX Option. *See* Rule 5.70.

[6] *See* Rules 4.21(a) and 5.72(b).

[7] Rules 5.72 through 5.74 describe the various auction mechanisms available for the trading of FLEX Options. A FLEX Order may be submitted for execution into an electronic or open outcry FLEX auction pursuant to Rule 5.72, or into a FLEX Automated Improvement Mechanism auction (''FLEX AIM Auction'') pursuant to Rule 5.73, or FLEX Solicitation Auction Mechanism auction (''FLEX SAM Auction'') pursuant to Rule 5.74.

[8] *See* Rule 4.21(b) for a description of the terms of a FLEX Option series that a Submitting FLEX Trader must include in a FLEX Order.

[9] *See* Rule 4.21(b)(6). While the specific minimums for the exercise price are not currently included in Rule 4.21(b)(6), that rule indicates that the System rounds the exercise price to the nearest minimum increment as set forth in Rule 5.4, and the Exchange has interpreted the rule to mean that the minimum increment for the exercise price of FLEX Options is the same as the minimum increment for bids and offers of FLEX Options. The term ''trade date'' as used in Rule 4.21(b)(6), as well as in the sentence for this footnote and throughout this rule filing, refers to the date on which the FLEX Option was bought or sold (*i.e.,* the date on which the FLEX Option trade occurs). Note that the capped monthly return of a FLEX Index Option that is Cliquet-settled must be expressed in dollars and cents. *See* Rule 4.21(b)(5)(B)(iv) for a description of Cliquet-settled FLEX Index Options.

[10] The Exchange determines the minimum increment for bids and offers on FLEX Options on a class-by-class basis. *See* Rule 5.4(c)(4).

[11] The proposed rule change will have no impact on the minimum increment for bids and offers for open outcry FLEX Orders and auction responses, which minimum increment for bids and offers will continue to be $0.01 (if the exercise price for the FLEX Option series is a fixed price) or 0.01% (if the exercise price for the FLEX Option series is a percentage of the closing value of the underlying equity security or index on the trade date). The proposed rule change adds language to clarify that these minimum increments for bids and offers will continue to apply to FLEX Orders and auction responses submitted to an open outcry auction. *See* proposed Rule 5.4(c)(4)(B).

[12] The proposed rule change will have no impact on the smallest increment for exercise prices for open outcry FLEX Orders and auction responses, which may be no smaller than $0.01 (if the exercise price for the FLEX Option series is a fixed price) or 0.01% (if the exercise price for the FLEX Option series is a percentage of the closing value of the underlying equity security or index on the trade date). The proposed rule change adds language to clarify that these minimum increments for bids and offers will continue to apply to FLEX Orders and auction responses submitted to an open outcry auction. *See* proposed Rule 4.21(b)(6)(A).

System rounds to the nearest minimum increment for bids and offers, as set forth in Rule 5.4) may be a fixed price expressed in terms of dollars and decimals or a specific index value, as applicable, or a percentage of the closing value of the underlying equity security or index, as applicable, on the trade date. As noted above, current Rule 5.4(c)(4) states that the Exchange may determine the minimum increment for bids and offers on a class-by-class basis, which may not be smaller than $0.01 or 0.01%, as applicable. The Exchange has historically interpreted that current Rule 4.21(b)(6), by reference to current Rule 5.4(c)(4), provides that exercise prices may similarly be in increments no smaller than $0.01 or 0.01%, as applicable, which smallest increment for exercise prices the Exchange may determine on a class-by-class basis. The proposed rule change amends Rule 4.21(b)(6) to codify this longstanding interpretation by expressly stating the actual permissible smallest increments for exercise prices and that the Exchange may determine the smallest increment for exercise prices on a class-by-class basis.

In connection with this proposed change to add precision to exercise prices and pricing of FLEX Options, the proposed rule change makes the following nonsubstantive changes to Rules 4.21(b)(6) and Rule 5.4(c)(4), which nonsubstantive changes further clarify differences between FLEX Option series with exercise prices expressed as fixed increments and percentages, as well as add current rule interpretations and general transparency to the Rules:

• The proposed rule change specifies the actual permissible minimum amounts for exercise prices for FLEX Equity Options or FLEX Index Options that are not Cliquet-settled rather than identifying them by reference to Rule 5.4, which defines permissible minimum increments for bids and offers. As noted above, current Rule 4.21(b)(6) states the exercise price (which the System rounds to the nearest minimum increment as set forth in Rule 5.4), which may be for a FLEX Equity Option or FLEX Index Option that is not Cliquet-settled, a fixed price expressed in terms of dollars and decimals or a specific index value, as applicable, or a percentage of the closing value of the underlying equity security or index, as applicable, on the trade date. As discussed above, the Exchange has historically interpreted this rule to mean that the smallest permissible increments for exercise prices of FLEX Options are the same as the minimum increments for bids and offers of FLEX Options, which smallest increments the Exchange may determine on a class-by-class basis (as the Exchange may do for minimum increments for bids and offers). Rather than identify the minimum increments for exercise prices by reference to the rule describing the minimum increments for bids and offers, the proposed rule change adds the language specifying the actual minimum increments for exercise prices for FLEX Equity Options and FLEX Index Options that are not Cliquet-settled, which minimum increments are the same as minimum increments for bids and offers. Specifically, the proposed rule change states that the exercise price may be in increments no smaller than (which language is taken from Rule 5.4(c)(4)) (1) for a FLEX Equity Option or FLEX Index Option that is not Cliquet-settled, (a) $0.001 (for FLEX Orders submitted to an electronic FLEX Auction) or $0.01 (for FLEX Orders and auction responses submitted to an open outcry auction), if the exercise price for the FLEX Option series is a fixed price, or (b) 0.0001% (for FLEX Orders and auction responses submitted to an electronic auction) or 0.01% (for FLEX Orders and auction responses submitted to an open outcry auction), if the exercise price for the FLEX Option series is a percentage of the closing value of the underlying equity security or index on the trade date. As discussed above, the proposed rule change amends the permissible minimum amounts for exercise prices for FLEX Orders submitted to an electronic FLEX Auction. However, the minimum permissible amounts of $0.01 and 0.01% for FLEX Options with fixed exercise prices and percentage exercise prices, respectively, submitted into open outcry FLEX Auctions added to Rule 4.21(b)(6) are the current minimum increments permissible for these FLEX Options. Therefore, the proposed rule change makes no substantive changes to the minimum increments of exercise prices for FLEX Orders submitted into open outcry FLEX Auctions. The Exchange believes this will make the rule regarding permissible exercise prices for FLEX Options more transparent and thus may eliminate potential confusion regarding permissible exercise prices.

• The proposed rule change adds to the end of Rule 4.21(b)(6) that the Exchange may determine the smallest increment for exercise prices of FLEX Options on a class-by-class basis. As discussed above, this is consistent with the Exchange's longstanding interpretation of the current Rule, which refers to the minimum increment for bids and offers as set forth in Rule 5.4 when identifying the minimum increments for exercise prices of FLEX Options. Rule 5.4(c)(4) states that the Exchange may determine the minimum increment for bids and offers on FLEX Options on a class-by-class basis, which may be no smaller than the amounts specified in that rule. Therefore, the Exchange has interpreted Rule 4.21(b)(6) to mean that those same provisions apply to the minimum increments for exercise prices for FLEX Options. The proposed rule change codifies this longstanding interpretation in the Rules, which the Exchange believes will make the rule regarding permissible exercise prices for FLEX Options more transparent and thus may eliminate potential confusion regarding permissible exercise prices.[13]

• The proposed rule change moves the parenthetical regarding the System rounding the exercise price to the nearest minimum increment for bids and offers in the class (as set forth in Rule 5.4) from the introductory clause in Rule 4.21(b)(6) to the end of subclause (A)(ii), and makes corresponding changes to Rules 5.3(e)(3) and 5.4(c)(4) by enclosing that language in a parenthetical so that it applies only to subclause (B) of each subparagraph. While not specified in the Rules, such rounding would only occur for exercise prices and bids and offers (as discussed below, the proposed rule change replaces ''bids and offers'' with ''transaction prices''), respectively, expressed as a percentage, so the proposed rule clarifies that it applies only for exercise prices and bids and offers, respectively, expressed as a percentage and specifies that the System rounds the actual exercise prices and final transaction prices,[14] respectively, to the nearest fixed price minimum increment for bids and offers in the class.

The proposed rule change also adds to the parenthetical in Rule 4.21(b)(6)(A)(ii) that the System rounds the ''actual'' exercise price to the nearest fixed price minimum increment to provide additional clarity to the provision, as the dollar value of an exercise price expressed as a percentage

[13] The Exchange believes this flexibility is appropriate to permit the Exchange to make determinations based on the market characteristics of different classes. The Exchange notes the rules of another options exchange similarly permit that exchange to determine on a class-by-class basis both minimum increments for exercise prices and premiums (*i.e.,* bids and offers) stated using a percentage-based methodology. *See, e.g.,* NYSE Arca, Inc. (''Arca'') Rule 5.32–O(e)(2)(C).

[14] Amendment No. 1 replaces the phrase ''bids and offers'' in this sentence with ''transaction prices'' to reflect the updated term in the rule text.

determined after the closing value is available would be rounded to the nearest minimum dollar value increment, which dollar value would represent the ultimate, ''actual'' exercise price.[15] Similarly, the proposed rule change adds to the proposed parentheticals in Rules 5.3(e)(3)(B) and 5.4(c)(4)(B) that the System rounds the ''final transaction prices'' to the fixed price minimum increment to the class, as the dollar value of the transaction price of a FLEX Option for which the bids and offers were expressed as a percentage (the ''final'') determined after the closing value is available would be rounded to the nearest fixed price minimum increment for the class (*e.g.,* the nearest $0.01, if that is the minimum determined for the class). This is the same rounding process that applies today for these options. The Exchange notes current Rules 5.3(e)(3)(B) and 5.4(c)(4)(B) indicate the System rounds bids and offers to the nearest minimum increment. However, because bids and offers during a FLEX Auction are ranked based on the percentage amounts of bids and offers (as discussed below), and thus the transaction price(s) at the conclusion of the auction will be a percentage amount, there will no longer be bids and offers to round once the closing value of the underlying on the trade date is available. Rather, the transaction price is rounded. The proposed rule change corrects this term in these parentheticals to more accurately reflect how the System currently works.

Currently, as clarified by these proposed rule changes (and the additional description regarding rankings of bids and offers in FLEX Auction, as discussed below), bids and offers expressed as a percentage of the closing value of the underlying on the trade date are ranked by the percentage amount for FLEX Option series for which the exercise price is expressed as such a percentage. As a result, the transaction ''price(s)'' at the conclusion of a FLEX Auction will be a percentage amount(s). Once the closing value of the underlying on the trade date is available, the System determines the exercise price and transaction price in a dollar amount using that closing value, and rounds each to the minimum dollar amount increment at that time. For example, suppose a FLEX Trader submits an order to buy 100 contracts of FLEX Option series ABC Mar 50.24% into a FLEX Auction. There are two responses, each to sell 100, with response 1 offering to sell at 7.01% and response 2 to sell at 7.03%. Response 1 is a better price for the buy order (*i.e.* is ranked higher than response 2), so response 1 executes against the buy order at the conclusion of the auction for a transaction price of 7.01% of the closing value of the underlying on that date. Following the close of trading, the closing price of ABC on the day of that trade is $47.63. At that time, the System determines the actual exercise price in dollars to be $23.93 (rounded from 23.929).[16] At that time, the System also determines the final transaction price in dollars to be $3.34 (rounded from 3.338).[17] The System currently works this way and will continue to work in this way upon implementation of the proposed rule change (if approved), except rounding will occur to three decimals instead of two for electronic FLEX Orders.

- In addition, the proposed rule change makes a clarifying, nonsubstantive change to Rule 5.3(e)(3). Rule 5.3(e)(3) currently states that bids and offers for FLEX Options must be expressed in (a) U.S. dollars and decimals, if the exercise price for the FLEX Option series is a fixed price, or (b) a percentage, if the exercise price for the FLEX Option series is a percentage of the closing value of the underlying equity security or index on the trade date, per unit of the underlying security or index, as applicable. The System rounds bids and offers to the nearest minimum increment. The proposed rule change clarifies in the proposed parenthetical in Rule 5.3(e)(3)(B) (described in the preceding bulleted paragraphs) that bids and offers would be in the applicable minimum increment as set forth in Rule 5.4. This is true today and merely incorporates a cross-reference to Rule 5.4, which describes permissible minimum increments for bids and offers. The Exchange believes the addition of this cross-reference will provide additional transparency and clarity to this Rule.

The proposed rule change also codifies in Rules 5.72(c)(3)(A) and (d)(2), 5.73(e), and 5.74(e) how FLEX Auction response bids and offers (as well as Initiating Orders and Solicitation Orders with respect to FLEX AIM Auctions and FLEX SAM Auctions, respectively) are ranked during the allocation process following each type of FLEX Auction (*i.e.,* electronic FLEX Auction, open outcry FLEX Auction, FLEX AIM Auction, and FLEX SAM Auction, respectively). FLEX Orders will always first be allocated to responses at the best price, as applicable.[18] With respect to responses to all types of FLEX Auctions for a FLEX Option series with an exercise price expressed as a dollar and decimal, the ''prices'' at which FLEX Traders submitting responses are competing are the dollar and decimal amounts of the response bids and offers entered as fixed amounts (as is the case with all non-FLEX Options), and the proposed rule change codifies this in the Rules. With respect to responses to all types of FLEX Auctions for a FLEX Option series with an exercise price expressed as a percentage, the ''prices'' at which FLEX Traders submitting responses are competing are the percentage values of the response bids and offers entered as percentages (which ultimately become a dollar value after the closing value for the underlying security or index, as applicable, is available), and the proposed rule change codifies this in the Rules. These are nonsubstantive changes, as they reflect how ranking following FLEX Auctions occurs today, and the Exchange believes these changes will provide additional transparency in the Rules.

The Exchange notes that responses to the Exchange's electronic FLEX Auctions are not visible to other FLEX Traders, and therefore FLEX Traders will not be able to compete by increasing or decreasing bids and offers, respectively, of other FLEX Traders by

[15] As discussed above, the dollar value minimum increment for bids and offers is either $0.001 (for FLEX Orders submitted into electronic FLEX Auctions) (as proposed) or $0.01 (for FLEX Orders submitted into open outcry FLEX Auctions).

[16] This Amendment No. 1 corrects a typo in the parenthetical in this sentence by updating ''23.939'' to ''23.929'' to reflect the actual calculated exercise price, which rounds to $23.93. Additionally, Amendment No. 1 adds the following sentence in this footnote to describe how the actual exercise price is calculated. Specifically, as set forth in Rule 4.21(b)(6), a FLEX Option series with a percentage exercise price reflects a percentage of the closing value of the underlying equity security or index, as applicable, on the trade date. Therefore, in this example, the actual exercise price is the percentage (50.24%) of the closing value of underlying ABC on the trade date ($47.63), which is 23.929, which the System rounds to $23.93. Contract multipliers are applied after any rounding occurs.

[17] This Amendment No. 1 adds this footnote to describe how the actual transaction price is calculated. Specifically, as set forth in Rule 5.4(c)(4), a FLEX Option series with a percentage bid or offer reflects a percentage of the closing value of the underlying equity security or index, as applicable, on the trade date. Therefore, in this example, the actual transaction price is the percentage (7.01%) of the closing value of underlying ABC on the trade date ($47.63), which is 3.338, which the System rounds to $3.34.

[18] The proposed rule change also clarifies this in Rule 5.72(d)(2) by adding a cross-reference to Rule 5.85(a)(1), which states that, with respect to open outcry trading on the Exchange's trading floor, bids and offers with the highest bid and lowest offer have priority. This is a nonsubstantive change that is currently true for open outcry FLEX Auctions, and the proposed rule change merely makes this explicit in Rule 5.72(d)(2), which cross-reference was previously inadvertently omitted from the Rules.

a minute increment.[19] The Exchange does not currently propose to add more precision for bids and offers and exercise prices for open outcry FLEX Auctions to avoid the risk of such competition because FLEX Traders in the trading crowd can hear the responses of others in the crowd. The Exchange understands that demand for the additional precision is primarily for electronic trading.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[20] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[21] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[22] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will protect investors and the public interest by providing investors with the ability to obtain more precise premiums and exercise prices for FLEX Options in electronic FLEX trading. Given the various trading and hedging strategies employed by investors and the importance of every penny, particularly with larger orders and orders in classes with significant notional values, this additional precision may provide them with more control over the prices at which their FLEX Orders trade and are exercised. The total price of an order for 10,000 contracts of a series will be much greater than (*i.e.,* 100 times) the total price of an order for 100 contracts of the same series, and therefore additional precision may impact that price. For example, suppose a FLEX Trader buys 1 ABC Mar 20 at 1.05%, and the closing price of ABC on the day of that trade is $50, making the final purchase price $0.53 (rounded from 0.525),[23] for a total of $53 after applying the 100 contract multiplier. Suppose another FLEX Trader buys 10,000 of the same series at the same price, making the total purchase price $530,000. With the proposed rule change, suppose each FLEX Trader instead paid 1.0455% (which decimal is currently not permissible and would have needed to be input as 1.05%), for a purchase price of $0.523 (rounded from 0.52275).[24] The total purchase price of the first trade would be $52.30 (down from $53), and the total purchase price of the second trade would be $523,000 (down from $530,000). The additional precision for the smaller order permitted the FLEX Trader to pay $0.70 less, while the additional precision for the larger order permitted the FLEX Trader to pay $7,000 less. This example demonstrates how the impact on larger-sized orders may be particularly significant given the larger total purchase price. The larger impact is similar for options with larger notional values. While additional decimals may be available for bids and offers and exercise prices for FLEX Options submitted into electronic auctions pursuant to the proposed rule change, FLEX options will otherwise continue to trade in the same manner as they do today.

By permitting FLEX Options to trade with similar precision currently available to customized options in the OTC market, the Exchange believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system by further improving a comparable alternative to the OTC market in customized options. By enhancing our FLEX trading platform to provide additional terms available in the OTC market but not currently available in the listed options market, the Exchange believes it may be a more attractive alternative to the OTC market. The Exchange believes market participants benefit from being able to trade customized options in an exchange environment in several ways, including but not limited to the following: (1) Enhanced efficiency in initiating and closing out positions; (2) increased market transparency; and (3) heightened contra-party creditworthiness due to the role of The Options Clearing Corporation (''OCC'') as issuer and guarantor of FLEX Options.

The Exchange does not believe that the proposed rule change to permit FLEX Traders to submit bids and offers in a ''sub-increment'' as small as $0.001 or 0.0001% (which bids and offers would be ranked for allocation purposes based on that four-decimal percentage value) as opposed to the current minimum of $0.01 or 0.01% for electronic FLEX auctions raises any of the risks the Securities and Exchange Commission (the ''Commission'') has previously raised with respect to ''sub-increment'' pricing. In its reproposal of the ''Sub-Penny Rule,''[25] the Commission stated that ''sub-penny quoting impedes transparency by reducing market depth at the national best bid or offer (''NBBO'') and increasing quote flickering.''[26] The Commission stated in its overview of the proposed Sub-Penny Rule that the rule ''would address the practice of 'stepping ahead' of *displayed* limited orders by trivial amounts'' and therefore ''further encourage the display of limit orders and improve the depth and liquidity of trading in NMS stocks.''[27] Specifically, the Commission identified the following problems caused by sub-pennies that the Sub-Penny Rule was designed to address when approving the Sub-Penny Rule:

- If investors' limit orders lose execution priority for a nominal amount, investors may over time decline to use them, thus depriving the markets of liquidity.
- When market participants can gain execution priority for a nominal amount, important customer protection rules such as exchange priority rules and the Manning Rule could be undermined.
- Flickering quotations that can result from widespread sub-penny pricing

[19] *See* Rules 5.72(c)(2)(D)(iv), 5.73(c)(5)(E), and 5.74(c)(5)(E).

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] *Id.*

[23] As described in the prior example above, any rounding of the final transaction price to the minimum fixed increment occurs following the close of trading on the trade date once the closing value of the underlying on that date is available, after the percentage of the underlying closing value is calculated.

[24] *Id.*

[25] The ''Sub-Penny Rule'' in Rule 612 of Regulation NMS states that no national securities exchange, national securities association, alternative trading system, vendor, or broker or dealer may display, rank, or accept from any person a bid or offer, an order, or an indication of interest in any NMS stock priced in an increment smaller than $0.01 if that bid or offer, order, or indication of interest is priced equal to or greater than $1.00 per share. The minimum increment for a bid or offer, an order, or an indication of interest in any NMS stock priced less than $1.00 per share is $0.0001. *See* 17 CFR 242.612. While Rule 612 applies only to NMS stocks and not options, no options exchange permits bids or offers on options to be less than $0.01.

[26] *See* Securities Exchange Act Release No. 50870, 69 FR 77423, 77484 (December 27, 2004) (proposed rules and amendments to joint industry plans).

[27] *Id.* at 77429 (emphasis added).

could make it more difficult for broker-dealers to satisfy their best execution obligations and other regulatory responsibilities.

• Widespread sub-penny quoting could decrease market depth and lead to higher transaction costs.

• Decreasing depth at the inside could cause institutions to rely more on execution alternatives away from the exchanges, potentially increasing fragmentation in the securities markets.[28]

The Commission, however, ''acknowledge[d] the possibility that the balance of costs and benefits could shift in a limited number of cases or as the markets continue to evolve.[29] While the Sub-Penny Rule is inapplicable to options trading, the Exchange understands the same concerns described above may exist in the options markets with respect to subincrement prices.

In the context of FLEX Option trading, there is no NBBO, as execution prices of FLEX Options are not required to consider the prices of options on other exchanges (thus there is no NBBO for FLEX Options). Additionally, there is no book for FLEX Options on the Exchange. As a result, there is no displayed liquidity (or market depth) in front of which interest may ''step ahead,'' and the concept of quote flickering would not arise in the Exchange's FLEX Options market. Additionally, the FLEX market is generally less liquid than the non-FLEX market. Trading in FLEX Options may be spread over a larger number of series than non-FLEX Options (due to FLEX options not being pre-established). As a result, trading interest in a particular series of FLEX Options may be limited, making markets in FLEX Options potentially less deep and liquid than in non-FLEX Options with the same underlying interest.[30] As a result, the Exchange does not believe the risk that sub-increment trading will lead to reduced market depth and liquidity in the FLEX market, as those may occur due to the nature of the FLEX market in general regardless of the pricing precision available. In fact, as discussed, the Exchange believes the proposed rule change to permit additional pricing precision for FLEX Options may provide market participants with additional flexibility to achieve their investment objectives on a listed exchange. These increased investment opportunities may ultimately add liquidity to the FLEX Options market.

Additionally, the Commission made clear that the prohibition of sub-penny quoting would ''deter the practice of stepping ahead of *exposed* trading interest by an economically insignificant amount.'' [31] No such practice is possible given that trading interest in FLEX Auctions is not exposed. FLEX Options submitted for electronic execution may only execute pursuant to an electronic auction in which the trading interest of competing FLEX Traders is not exposed as set forth in Rules 5.72, 5.73, and 5.74. As noted above, responses to the Exchange's electronic FLEX Auctions are not visible to other FLEX Traders.[32] Therefore, there will generally be no displayed liquidity to which other FLEX Traders may respond by purposefully increasing or decreasing their bids and offers, respectively, of other FLEX Traders by a trivial amount. Unlike limit orders, auction responses are not intended to serve a price-setting function. Therefore, the Exchange does not believe that the proposed ''sub-increment'' for electronic FLEX Auctions will diminish liquidity in these auctions as the Commission believes sub-penny quoting may cause with respect to displayed limit orders that do serve a price-setting function in the displayed market.[33] As discussed above, the purpose of FLEX Options is to add transparency to the market by encouraging the trading of customized options on the Exchange rather than in OTC. As noted above, trading in FLEX Options may be spread over a larger number of series than non-FLEX Options (due to FLEX options not being pre-established). As a result, trading interest in a particular series of FLEX Options may be limited, making markets in FLEX Options potentially less deep and liquid than in non-FLEX Options with the same underlying interest.[34] The Exchange believes the proposed enhancement to FLEX trading in this rule filing may encourage additional Exchange trading and liquidity in these options, which benefits all investors.

While it is possible that the ultimate result is that a FLEX Trader's response in an electronic FLEX Auction may lose execution priority if the response of another FLEX Trader is better by a small amount, it is just as possible the FLEX Trader may gain execution priority by a small amount. Because a FLEX Trader would not know the prices of other responses, the FLEX Trader could not submit a response with the purpose of increasing the prices of other responses by an economically insignificant amount. The purpose of not displaying auction responses of other auction participants is to encourage all FLEX Traders to submit their best-priced responses.[35] As demonstrated above, even small price changes can create a significant price difference. The Exchange does not believe the proposed rule change will discourage FLEX Traders from providing liquidity to electronic FLEX Auctions, because the prices of their responses are not available to other FLEX Traders to use to step ahead by a small amount (and thus ''piggyback'' off of pricing done by other investors) in order to gain execution priority. The Commission itself acknowledged the difference between use of a sub-increment in the context of an auction and in the context of displayed liquidity in the book. Specifically, in response to a commenter arguing that the Commission should prohibit the Boston Options Exchange (''BOX'') from using ''sub-increment'' pricing in its price improvement period (''PIP'') auction,[36] the Commission states that it did ''not believe that the PIP raise[d] the same problems caused by sub-penny quotations of non-option securities . . .'' because the use of the sub-increment was in an auction rather than public quotations.[37]

While equities and options may generally not trade in increments smaller than $0.01,[38] there are exceptions to this restriction for

[28] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37551—52 (June 29, 2005) (''Sub-Penny Approval'').

[29] *Id.* at 37553.

[30] *See* Options Disclosure Document (''ODD'') at pages 77—78.

[31] *See* Securities Exchange Act Release No. 50870, 69 FR 77423, 77457 (December 27, 2004) (proposed rules and amendments to joint industry plans) (emphasis added).

[32] The Exchange does not disseminate the auction prices for any FLEX Auctions (except the FLEX SAM Auction). *See* Rules 5.72(c)(2)(A) and 5.73(c)(2); *see also* 5.74(c)(2).

[33] *See supra* note 24 [sic] at 77457.

[34] *See* Options Disclosure Document (''ODD'') at pages 77—78.

[35] FLEX Traders are permitted to submit multiple responses at multiple prices).

[36] BOX was permitting penny increments in this price improvement auction despite the standard increments for options being $0.05 and $0.10. *See* Securities Exchange Act Release No. 49068 (January 13, 2004), 69 FR 2775 (January 13, 2004) (SR–BSE–2002–15) (order approving PIP auctions that permit orders and responses be submitted into the auctions in penny increments).

[37] *See supra* note 24 [sic] at 77459. The Exchange acknowledges that it submitted the comment arguing for prohibition of the use of sub-increment pricing in BOX's PIP auction. However, the Commission approved it as being consistent with the Exchange Act (and the Exchange itself has similar price improvement auctions that permit penny pricing in options with minimum increments of $0.05 and $0.10), and the Commission disagreed with the Exchange's argument.

[38] As set forth in Rule 5.4, some options classes may trade in increments of $0.01 or $0.05 (several classes may trade in increments of $0.01 for all strikes), while other classes may trade in increments of $0.05 or $0.10. Complex orders may generally trade in increments of $0.01, and FLEX class may trade in increments of $0.01 or 0.01%.

specific, limited purposes. As noted above, the minimum increment for a bid or offer, an order, or an indication of interest in any NMS stock priced less than $1.00 per share is $0.0001.[39] Sub-penny cabinet orders may execute on the Exchange to accommodate closing transactions in options.[40] In both cases, sub-increment pricing permits more appropriate prices to apply to lower-valued stocks and options.

In addition, various equity exchanges offer retail price improvement programs, pursuant to which retail orders may be entered in increments of $0.001 if the prices of those retail orders increase the NBBO at the time of entry (the prices of the orders would be nondisplayed), despite the $0.01 minimum increment for all other orders.[41] While the purpose of these retail price improvement programs was to create additional price improvement opportunities for retail investors,[42] the impetus for the programs was similar to the purpose of the proposed rule change. Specifically, the Commission recognized that most marketable retail order flow executed in OTC markets without reaching a public exchange, therefore limiting market participants that had the opportunity to interact with that order flow.[43] The Commission indicated it believed creating additional price improvement opportunities for retail investors by permitting those orders to be submitted at subpenny prices (as was typical in the OTC market), the program was ''reasonably designed to attract retail order flow to the exchange environment.'' [44] The Commission also noted the benefits to institutional investors that may result from opportunities to interact with that order flow that such investors were not then able to reach in the OTC market.[45] Ultimately, the Commission found the Program would benefit the marketplace by bringing more information about retail orders to the marketplace and would enhance competition among market participants and encourage competition amongst exchange venues.[46]

Like the BYX retail price improvement program (and other similar programs), the proposed rule change is intended to attract order flow that currently executes in the OTC market to an exchange by permitting competition on the exchange for that order flow to occur with the same terms available in the OTC market. FLEX Traders on the Exchange are not currently able to interact with order flow for many options that could otherwise trade as FLEX Options because it is routinely executed in the OTC market where sub-increment executions are available so they can obtain the benefits of pricing precision as described above. The Exchange believes the proposed rule change is reasonably designed, limited to FLEX Options (which represents a small percentage of Exchange volume), to attract FLEX Option order flow to the Exchange, which would add transparency to the market for these options, as well as provide those options with the benefits of trading on an exchange (which benefits are described above).

Like the retail price improvement programs, the Exchange believes the proposed rule change is a case in which the benefits of subincrement pricing due to evolving markets outweigh any potential costs. The benefits of attracting FLEX Option order flow to an exchange are outlined above. Exchanges are unable to currently compete to equal footing with the OTC market for a variety of factors, including due to the current lack of availability of subincrement pricing. The proposed rule change is a limited exception to the current minimum of penny increment pricing on the Exchange, which is reasonably designed to minimize the concerns the Commission has previously raised with respect to subincrement pricing. Because there is no book, and thus no quotes or resting limit orders, in the FLEX Options market, the Exchange believes there is de minimis, if any, risk of reducing incentives for investors to display limit orders or for quote-flickering and reduced market depth. In fact, by attracting more FLEX Option order flow to the Exchange, the Exchange believes the proposed rule change could result in greater order interaction and liquidity in the FLEX Options market. As noted above, because all FLEX Options may only execute in auctions in which responses are not disseminated, the Exchange believes the proposed rule change does not encourage market participants to step ahead of competing responses to gain an insignificant price improvement because those prices are not displayed. The proposed rule change is designed to attract order flow away from the alternative of OTC execution, and, therefore, the Exchange does not believe the proposed rule change will cause increased fragmentation (and in fact it may reduce this fragmentation). Because the proposed rule change is limited to FLEX Options and given the structure of the FLEX market on the Exchange, the Exchange believes the benefits of increasing the potential to compete with OTC markets for FLEX orders in order to bring additional transparency to executions occurring off-exchange today and to provide those orders with the benefits of trading on an exchange far outweigh any risks related to subincrement pricing that may exist in the FLEX Options market (which, as described above, the Exchange believes are minimal). As a result, the Exchange believes the proposed rule change will benefit investors and remove impediments to and perfect the mechanism of a free and open market and a national market system, as well as promote just and equitable principles of trade and promote competition by permitting the Exchange to compete on similar terms with the OTC market.

The Exchange believes the proposed rule change to describe how bids and offers in FLEX Auctions for FLEX Option series are ranked and allocated will remove impediments to and perfect the mechanism of a free and open market and a national market system and protect investors and the public interest by increasing the transparency in the Rules regarding the allocation of FLEX Orders at the conclusion of FLEX Auctions. The proposed rule change codifies that the term ''price'' in the rules regarding allocations following FLEX Auctions refers to the dollar and decimal amount of bids and offers submitted as a fixed amount (as is the case for all non-FLEX Options and which as proposed may be as small as $0.001 for FLEX Options), and the percentage value (which as proposed may be as small as 0.0001%) of bids and

[39] *See* 17 CFR 242.612.

[40] *See* Rule 5.85(h).

[41] *See, e.g.,* Cboe BYX Exchange, Inc. (''BYX'') Rule 11.24. The Exchange notes that multiple retail orders will be ranked for priority purposes based on their prices (including any subpenny prices).

[42] It is common for markets to generally distinguish between retail investors and other traders; however, it is also common for markets to generally distinguish between FLEX trading and non-FLEX trading. For example, as otherwise discussed in this filing, the manner in which FLEX Options trades (via auction only) differs from the manner in which non-FLEX options trade (a combination of a book into which orders may be submitted as well as auctions). Additionally, as noted above, all FLEX Options may trade in pennies, while only certain non-FLEX Options (with certain strikes) may trade in pennies.

[43] *See* Securities Exchange Act Release No. 68303 (November 27, 2012), 77 FR 71652, 71655 (December 3, 2012) (SR–BYX–2012–019) (''BYX Approval Order''). The BYX retail price improvement program was initially approved as a pilot program; however, the Commission later approved it to become a permanent program. *See* Securities Exchange Act Release No. 87154 (September 30, 2019), 84 FR 53183 (October 4, 2019) (SR–CboeBYX–2019–014).

[44] *Id.* at 71656.

[45] *Id.*

[46] *Id.* at 71657.

offers submitted as percentages. As percentages ultimately reflect a price in dollars and cents, and thus allocation of a FLEX Order to the highest percentage bids and lowest percentage offers still results in allocation of that order to the best prices in the same manner as bids and offers in dollars and cents. For example, a bid of 1.05% will be for a higher dollar value than a bid of 1.04%, because a higher percentage of a number will have a higher value than a lower percentage of that same number. This is a reasonable allocation that ensures highest priced bids and offers receive first priority (and is the same as how dollar-priced bids and offers are ranked), which protects investors.

The Exchange believes the proposed nonsubstantive changes, codification of a longstanding interpretation, and correction of terms described above enhance the readability of and provide clarity to the applicable provisions, which increases the transparency of the Rules and ultimately benefits investors.

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 purposes of the Act. The Exchange does not believe that the proposed rule change to increase precision for bids and offers and exercise prices for electronic FLEX Auctions will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because the same bid and offer and exercise price increments will be available to all FLEX Traders. While the same precision will not be available in open outcry FLEX Auctions, all FLEX Traders have the ability to submit FLEX Orders for electronic execution if they desire to trade with additional precision.[47] The Exchange does not believe that the proposed rule change to increase the precision for bids and offers and exercise prices for FLEX Options submitted for electronic execution will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, because while additional decimals may be available for bids and offers and exercise prices for electronic auctions, FLEX options will continue to trade in the same manner as they do today. While FLEX markets may be less liquid than non-FLEX markets for options with the same underlying, the Exchange believes the proposed rule change may increase liquidity in the FLEX markets. To the extent the proposed rule change makes the Exchange a more attractive trading venue for market participants on other exchanges, those market participants may elect to become Exchange market participants.

The Exchange believes that the proposed rule change may relieve any burden on, or otherwise promote, competition. The Exchange believes this is an enhancement to a comparable alternative to the OTC market in customized options. By enhancing our FLEX trading platform to provide additional pricing terms that are available in the OTC market but not currently available in the listed options market, the Exchange believes it may be a more attractive alternative to the OTC market. The Exchange believes market participants benefit from being able to trade customized options in an exchange environment in several ways, including but not limited to the following: (1) Enhanced efficiency in initiating and closing out position; (2) increased market transparency; and (3) heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor of FLEX Options. The Exchange believes these benefits in addition to the benefits of precision pricing described above far outweigh the minimal (if any) risks of sub-increment pricing in the FLEX market.

The nonsubstantive proposed rule changes, as well as the codification of an interpretation and term correction, are not intended for competitive purposes, but rather to increase transparency in the Rules by codifying current System functionality and practice with respect to FLEX Option bids and offers. These changes do not modify how FLEX Options trade on the Exchange and merely provide enhanced clarity and readability to the Rules.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be 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, as modified by Amendment No. 1, 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–CBOE–2020–106 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–CBOE–2020–106. 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

[47] Options generally have different minimum increments in the same class. *See* Rule 5.4.

submissions should refer to File Number SR–CBOE–2020–106, and should be submitted on or before December 28, 2020.[48]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26678 Filed 12–3–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90528; File No. SR–NYSEArca–2020–80]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving a Proposed Rule Change, as Modified by Amendment No. 2, To List and Trade Shares of Alger Mid Cap 40 ETF and Alger 25 ETF Under Rule 8.900–E

November 30, 2020.

I. Introduction

On September 1, 2020, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the Alger Mid Cap 40 ETF and Alger 25 ETF (individually, ''Fund,'' and collectively, ''Funds'') under NYSE Arca Rule 8.900–E (Managed Portfolio Shares). The proposed rule change was published for comment in the **Federal Register** on September 21, 2020.[3]

On October 7, 2020, NYSE Arca filed Amendment No. 1 to the proposed rule change.[4] On October 29, 2020, pursuant to Section 19(b)(2) of the Act,[5] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[6] On November 5, 2020, NYSE Arca filed Amendment No. 2 to the proposed rule change.[7] The Commission has received no comments on the proposal. This order grants approval of the proposed rule change, as modified by Amendment No. 2.

II. The Exchange's Description of the Proposal, as Modified by Amendment No. 2[8]

NYSE Arca Rule 8.900–E(b)(1) requires the Exchange to file separate proposals under Section 19(b) of the Act before listing and trading any series of Managed Portfolio Shares on the Exchange. Accordingly, the Exchange has submitted this proposal to list and trade the Shares of the Funds. The Shares will be issued by The Alger ETF Trust (''Trust''), a business trust organized under the laws of the state of Massachusetts and registered with the Commission as an open-end management investment company.[9] The investment adviser to each Fund will be Fred Alger Management, LLC (''Adviser''), and Fred Alger & Company, LLC will serve as the distributor of each of the Fund's Shares.

A. Description of the Funds

Each Fund's holdings will conform to the permissible investments as set forth in the Exemptive Application and Exemptive Order and the holdings will be consistent with all requirements in the Exemptive Application and Exemptive Order.[10]

Alger Mid Cap 40 ETF

The Fund's primary objective is to seek long-term capital appreciation. The Fund will primarily invest in equity securities listed on U.S. exchanges, including common or preferred stocks, of mid-cap growth companies. The Fund will generally own approximately 40 holdings.

Alger 25 ETF

The Fund's primary objective is to seek long-term capital appreciation. The Fund will primarily invest in equity securities of growth companies of any market capitalization listed on U.S. exchanges, including common or preferred stocks. The Fund will generally own approximately 25 holdings.

B. The Funds' Investment Restrictions

Each Fund's investments, including derivatives, will be consistent with its investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage). That is, for each Fund, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2X or –3X) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A).[11]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 2, to list and trade the Shares is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[12] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(5) of the Act,[13] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

For each series, the Exchange will establish a minimum number of Shares

[48] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89869 (September 15, 2020), 85 FR 59354.

[4] Amendment No. 1, which amended and replaced the proposed rule change in its entirety, is available on the Commission's website at: *https://www.sec.gov/comments/sr-nysearca-2020-80/srnysearca202080.htm.*

[5] 15 U.S.C. 78s(b)(2).

[6] *See* Securities Exchange Act Release No. 90286, 85 FR 70216 (November 4, 2020).

[7] Amendment No. 2, which amended and replaced the proposed rule change, as modified by Amendment No. 1, in its entirety, is available on the Commission's website at: *https://www.sec.gov/comments/sr-nysearca-2020-80/srnysearca202080.htm.*

[8] Additional information regarding the Funds, the Trust (defined *infra*), and the Shares can be found in Amendment No. 2, *id.,* and the Registration Statement, *infra* note 9.

[9] The Trust is registered under the Investment Company Act of 1940 (''1940 Act''). On August 17, 2020, the Trust filed a registration statement on Form N–1A under the Securities Act of 1933 and the 1940 Act for the Funds (File No. 811–23603) (''Registration Statement''). The Commission issued an order granting exemptive relief to the Trust (''Exemptive Order'') under the 1940 Act on May 19, 2020 (Investment Company Act Release No. 33869) in response to the Trust's application (''Exemptive Application'') for exemptive relief (File No. 812–15117).

[10] Pursuant to the Exemptive Order, the only permissible investments for a Fund are the following that trade on a U.S. exchange contemporaneously with Shares of a Fund: Exchange-traded funds (''ETFs''), exchange-traded notes, exchange-listed common stocks, exchange-traded American Depositary Receipts, exchange-traded real estate investment trusts, exchange-traded commodity pools, exchange-traded metals trusts, exchange-traded currency trusts and exchange-traded futures, as well as cash and cash equivalents (short-term U.S. Treasury securities, government money market funds, and repurchase agreements).

[11] Each Fund's broad-based securities benchmark index will be identified in a future amendment to the Registration Statement following that Fund's first full calendar year of performance.

[12] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 15 U.S.C. 78f(b)(5).

required to be outstanding at the time of commencement of trading on the Exchange.[14]

The Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer.[15] The Adviser has implemented and will maintain a ''fire wall'' with respect to its broker-dealer affiliate regarding access to information concerning the composition of, and changes to, a Fund's portfolio and Creation Basket.[16] Any person related to the Adviser or the Trust who makes decisions pertaining to a Fund's portfolio composition or that has access to information regarding a Fund's portfolio or changes thereto or the Creation Basket will be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding such portfolio or changes thereto and the Creation Basket.[17] Further, any person or entity, including an AP Representative,[18] custodian, Reporting Authority, distributor, or administrator, who has access to information regarding the Fund's portfolio composition or changes thereto or its Creation Basket, must be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the applicable Fund portfolio or changes thereto or the Creation Basket.[19] Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity must erect and maintain a ''fire wall'' between the person or entity and the broker-dealer with respect to access to information concerning the composition of and/or changes to such Fund's portfolio or Creation Basket.[20]

The Exchange states that trading in the Shares will be subject to the Exchange's surveillance procedures for derivative products, and that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws.[21] NYSE Arca Rule 8.900–E(b)(3) requires each Fund's investment adviser to, upon request by the Exchange, or the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, to make available to the daily portfolio holdings of each series of Managed Portfolio Shares. The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees.[22] The Commission notes that, similarly, FINRA Rule 9910(d) generally prohibits FINRA employees from disseminating or disclosing, for a purpose unnecessary to the performance of FINRA job responsibilities any nonpublic information obtained in the course of his or her employment.

The Commission also finds that the proposal is consistent with Section 11A(a)(1)(C)(iii) of the Act,[23] which sets forth Congress's finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. The Commission believes that the proposal is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading in the Shares when a reasonable degree of certain pricing transparency cannot be assured. As such, the Commission believes the proposal is reasonably designed to maintain a fair and orderly market for trading the Shares.

Specifically, as required by NYSE Arca Rule 8.900–E(d)(1)(B), the Exchange will obtain a representation from the issuer that the net asset value (''NAV'') per Share of each Fund will be calculated daily and will be made available to all market participants at the same time.[24] Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services.[25] Quotation and last-sale information for the Shares will be available via the Consolidated Tape Association high-speed line.[26] In addition, the Verified Intraday Indicative Value (''VIIV''), as defined in NYSE Arca Rule 8.900–E(c)(2),[27] will be widely disseminated by the Reporting Authority and/or one or more major market data vendors in one second intervals during the Exchange's Core Trading Session.[28] Moreover, the Funds' website will include a form of the prospectus for each Fund that may be downloaded. The Funds' website will include additional quantitative information updated on a daily basis, including, for each Fund, the prior Business Day's NAV, market closing price or mid-point of the bid/ask spread at the time of calculation of such NAV (''Bid/Ask Price''),[29] and a calculation of the premium and discount of the market closing price or Bid/Ask Price against the NAV. The website and information will be publicly available at no charge.[30]

The Commission also notes that the Exchange's rules regarding trading halts help to ensure the maintenance of fair and orderly markets for the Shares. Specifically, the Exchange may consider all relevant factors in exercising its discretion to halt trading in the Shares, and will halt trading in the Shares under the conditions specified in NYSE Arca Rule 7.12–E. Trading in the Shares will be subject to NYSE Arca Rule 8.900–E(d)(2)(C), which sets forth circumstances under which trading in the Shares will be halted. Specifically, NYSE Arca Rule 8.900–E(d)(2)(C)(i) provides that 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

[14] *See* NYSE Arca Rule 8.900–E(d)(1)(A).

[15] *See* Amendment No. 2, *supra* note 7, at 6.

[16] *See id. See also* NYSE Arca Rule 8.900–E(c)(5) (defining ''Creation Basket'').

[17] *See* Amendment No. 2, *supra* note 7, at 6. Furthermore, the Exchange represents that in the event that (a) the Adviser becomes registered as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, the Adviser will implement and maintain a fire wall with respect to personnel of the broker-dealer or broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio and/or Creation Basket. *See id.* at 6.

[18] *See* NYSE Arca Rule 8.900–E(c)(5) (defining ''AP Representative'').

[19] *See* NYSE Arca Rule 8.900–E(b)(5).

[20] *See id.*

[21] *See* Amendment No. 2, *supra* note 7, at 15.

[22] *See id.*

[23] 15 U.S.C. 78k-1(a)(1)(C)(iii).

[24] *See* Amendment No. 2, *supra* note 7, at 19.

[25] *See id.* at 12.

[26] *See id.*

[27] NYSE Arca Rule 8.900–E(c)(2) defines the term ''Verified Intraday Indicative Value'' as the indicative value of a Managed Portfolio Share based on all of the holdings of a series of Managed Portfolio Shares as of the close of business on the prior business day and, for corporate actions, based on the applicable holdings as of the opening of business on the current business day, priced and disseminated in one second intervals during the Core Trading Session by the Reporting Authority. NYSE Arca Rule 8.900–E(c)(8) defines the term ''Reporting Authority'' with respect to a particular series of Managed Portfolio Shares as the Exchange, an institution, or a reporting service designated by the Exchange or by the exchange that lists a particular series of Managed Portfolio Shares (if the Exchange is trading such series pursuant to unlisted trading privileges), as the official source for calculating and reporting information relating to such series, including, but not limited to, the NAV, the VIIV, or other information relating to the issuance, redemption, or trading of Managed Portfolio Shares. A series of Managed Portfolio Shares may have more than one Reporting Authority, each having different functions.

[28] *See* NYSE Arca Rule 8.900–E(d)(2)(A). *See* Amendment No. 2, *supra* note 7, at 12.

[29] The Bid/Ask Price of a Fund's Shares will be the mid-point between the current national best bid and offer at the time of calculation of such Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Funds or their service providers. *See* Amendment No. 2, *supra* note 7, at 12, n. 7.

[30] *See id.*

market conditions or for reasons that, in the view of the Exchange, make trading in the series of Managed Portfolio Shares inadvisable. These may include: (a) The extent to which trading is not occurring in the securities and/or the financial instruments composing the portfolio; or (b) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[31] NYSE Arca Rule 8.900–E(d)(2)(C)(ii) provides that, if the Exchange becomes aware that: (i) The VIIV of a series of Managed Portfolio Shares is not being calculated or disseminated in one second intervals, as required; (ii) the NAV with respect to a series of Managed Portfolio Shares is not disseminated to all market participants at the same time; (iii) the holdings of a series of Managed Portfolio Shares are not made available on at least a quarterly basis as required under the 1940 Act; or (iv) such holdings are not made available to all market participants at the same time (except as otherwise permitted under the applicable Exemptive Order or no-action relief granted by the Commission or Commission staff to the Investment Company with respect to the series of Managed Portfolio Shares), it will halt trading in such series until such time as the VIIV, the NAV, or the holdings are available, as required.

In support of this proposal, the Exchange has also made the following representations:

(1) The Shares will conform to the initial and continued listing criteria under NYSE Arca Rule 8.900–E.

(2) The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities.[32]

(3) Prior to the commencement of trading, the Exchange will inform its members in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares.[33]

(4) FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, will communicate as needed regarding trading in the Shares and certain exchange-traded instruments with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and certain exchange-traded instruments from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

(5) The Exchange represents that, for initial and/or continued listing, each Fund will be in compliance with Rule 10A–3 under the Act.[34]

This approval order is based on all of the Exchange's statements and representations set forth above and in Amendment No. 2 to the proposed rule change. Additionally, the Exchange states that all statements and representations made in its proposal regarding (a) the description of the portfolio or reference assets, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules shall constitute continued listing requirements for listing the Shares on the Exchange, as provided under NYSE Arca Rule 8.900–E(b)(1). The issuer of the Shares will be required 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 Act, the Exchange will surveil for compliance with the continued listing requirements. If a Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).[35]

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(5) of the Act[36] and Section 11A(a)(1)(C)(iii) of the Act[37] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[38] that the proposed rule change (SR–NYSEArca–2020–80), as modified by Amendment No. 2, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26673 Filed 12–3–20; 8:45 am]

BILLING CODE 8011–01–P

[31] The Exemptive Application provides that the Investment Company or their agent will request that the Exchange halt trading in the applicable series of Managed Portfolio Shares where: (i) The intraday indicative values calculated by the calculation engines differ by more than 25 basis points for 60 seconds in connection with pricing of the VIIV; or (ii) holdings representing 10% or more of a series of Managed Portfolio Shares' portfolio have become subject to a trading halt or otherwise do not have readily available market quotations. Any such requests will be one of many factors considered in order to determine whether to halt trading in a series of Managed Portfolio Shares, and the Exchange retains sole discretion in determining whether trading should be halted. As provided in the Exemptive Application, each series of Managed Portfolio Shares would employ a pricing verification agent to continuously compare two intraday indicative values during regular trading hours in order to ensure the accuracy of the VIIV. *See id.* at 14, n. 21.

[32] *See* Amendment No. 2, *supra* note 7, at 14.

[33] The Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares; (2) NYSE Arca Rule 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) how information regarding the VIIV is disseminated; (4) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; (5) trading information; and (6) that the portfolio holdings of the Shares are not disclosed on a daily basis. *See id.* at 15.

[34] *See id.* at 7, n. 7.

[35] *See id.* at 15.

[36] 15 U.S.C. 78f(b)(5).

[37] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[38] 15 U.S.C. 78s(b)(2).

[39] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90529; File No. SR–NYSEArca–2020–100]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Perth Mint Physical Gold ETF

November 30, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 20, 2020, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II 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 reflect (i) a change in the sponsors and the custodian of the Perth Mint Physical

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

Gold ETF, which will be renamed as the Goldman Sachs Physical Gold ETF[4] (''Trust''), (ii) the elimination of an investor's ability to take delivery of Physical Gold, and (iii) in connection with the change of custodian, the removal of the Government Guarantee, and to amend certain other representations in the proposed rule change filed with and approved by the Securities and Exchange Commission (''Commission'') relating to listing and trading of Shares of the Trust on the Exchange. Shares of the Trust have been approved by the Commission for listing and trading on the Exchange under NYSE Arca Rule 8.201–E.[5] The proposed rule 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 Commission has approved a proposed rule change relating to listing and trading on the Exchange of shares (''Shares'') of the Trust for listing and trading on the Exchange under NYSE Arca Rule 8.201–E (''Commodity-Based Trust Shares'').[6] The Exchange proposes to reflect (i) a change in the sponsors and the custodian of the Trust, (ii) the elimination of an investor's ability to take delivery of Physical Gold, and (iii) in connection with the change of custodian, the removal of the Government Guarantee, and to amend certain other representations in the proposed rule change filed with and approved by the Commission relating to listing and trading of Shares of the Trust on the Exchange.[7] The Trust will continue to comply with all initial and continued listing requirements under NYSE Arca Rule 8.201–E. Except for the changes noted below, all other representations made in the Prior Releases remain unchanged.[8]

Change to the Trust's Investment Objective

The First Prior Notice stated that the Trust's primary objective will be to provide investors with an opportunity to invest in gold through the Shares, have the gold securely stored by Gold Corporation and, if requested by an investor, deliver Physical Gold to such investor in exchange for its Shares. The Second Prior Release stated, however, that, because investors redeeming Shares would deliver Shares to the Gold Corporation rather than to the Trust, the Trust's primary objective will be to provide investors with an opportunity to invest in gold through the Shares and have the gold securely stored by Gold Corporation; and that the Gold Corporation rather than the Trust will be the entity that is responsible for and delivers Physical Gold to investors in exchange for Shares.

The Exchange proposes to change these representations regarding the Trust's investment objective to state that the Trust's investment objective is for the Shares to reflect the performance of the price of gold less the expenses of the Trust's operations, thus deleting reference to delivery of Physical Gold to an investor in exchange for Shares.

Change to Custodian and Sponsors

The Prior Notice stated that the sponsors of the Trust are the Gold Corporation and Exchange Traded Concepts, LLC. The Exchange proposes to change this representation to state that the Trust's sponsor (''Sponsor'') will be Goldman Sachs Asset Management, L.P. Goldman Sachs Asset Management, L.P. will take on the responsibilities previously performed by both the Gold Corporation (in its role as custodial sponsor) and Exchange Traded Concepts, LLC (in its role as administrative sponsor).[9] Although the sponsors of the Trust will change upon the closing of the Sponsorship Transfer Agreement, the Trust itself will remain in place and continue to issue and redeem Shares in Creation Unit sizes to Authorized Participants.[10]

[4] Upon the closing of the Sponsorship Transfer Agreement (defined in note 7, *infra*), the name of the Trust will be changed from ''Perth Mint Physical Gold ETF'' to ''Goldman Sachs Physical Gold ETF''.

[5] *See* note 6, *infra.*

[6] *See* Securities Exchange Act Release Nos. 82372 (December 21, 2017), 82 FR 61601 (December 28, 2017) (SR–NYSEArca–2017–140) (NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To List and Trade Shares of the Perth Mint Physical Gold ETF Trust Under NYSE Arca Rule 8.201–E) (''First Prior Notice''); 82593 (January 26, 2018), 83 FR 4718 (February 1, 2018) (SR–NYSEArca–2017–140) (Order Approving a Proposed Rule Change To List and Trade Shares of the Perth Mint Physical Gold ETF Trust Pursuant to NYSE Arca Rule 8.201–E) (''Prior Order'' and, together with the Prior Notice, the ''First Prior Releases''). See also, Securities Exchange Act Release No. 83248 (May 15, 2018), 83 FR 23494 (May 21, 2018) (SR–NYSEArca–2018–32) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Proposed Operation of the Perth Mint Physical Gold ETF Trust) (''Second Prior Release'' and, together with the First Prior Releases, the ''Prior Releases'').

[7] On June 11, 2019 the Trust filed with the Commission a registration statement on Form S–1 under the Securities Act of 1933 relating to the Trust (File No. 333- 224389) (''Registration Statement''). The Registration Statement was declared effective by the SEC on June 20, 2019. The description of the operation of the Trust herein is based, in part, on the Registration Statement. The procedures described in this proposed rule change will not be implemented until such proposed rule change is effective and operative and such changes will be reflected in a prospectus to the Registration Statement. On September 29, 2020, Perth Mint Physical Gold Trust filed with the Commission Form 8–K (the ''8–K'') under the Act relating to an agreement, also dated September 29, 2020, to transfer the role of sponsor from Gold Corporation and Exchange Traded Concepts, LLC to Goldman Sachs Asset Management, L.P. (such agreement, the ''Sponsorship Transfer Agreement'').

[8] *See* note 6, *supra.* All terms referenced but not defined herein are defined in the Prior Releases.

[9] All references in the Prior Releases to ''Sponsors'' would be replaced by ''Sponsor''. In addition, reference to ''Administrative Sponsor'' in the Prior Releases would be replaced by ''Sponsor'', as applicable.

[10] The Second Prior Release stated that the Trust will issue and redeem ''Baskets'' equal to a block of 50,000 Shares and that the size of a Basket is subject to change. In the Registration Statement, the Trust described its change of the size of a Basket to 25,000 Shares. The Second Prior Release stated further that a reduction in the size of a Basket may provide potential benefits to investors by facilitating additional creation and redemption activity in the Shares, thereby potentially resulting in increased secondary market trading activity, tighter bid/ask spreads and narrower premiums or discounts to net asset value (''NAV''). The Trust's change to a Basket size of 25,000 Shares is consistent with the August 8, 2018 letter from the Division of Trading and Markets granting no-action relief to certain commodity-based investment vehicles from Rules 101 and 102 of Regulation M under the Act. See footnote 2 to letter, dated August 8, 2018, from Josephine J. Tao, Assistant Director, Division of Trading and Markets, to Eric Simanek, Sullivan & Worcester LLP. The Exchange notes that the Commission has approved the listing and trading of other issues of Commodity-Based Trust Shares that have applied a minimum ''Creation Unit'' size of less than 50,000 shares. *See, e.g.,* Securities Exchange Act Release Nos. 82249 (December 8, 2017), 82 FR 58884 (December 14, 2017) (SR–NYSEArca–2017–110) (Notice of Filing of Amendment No. 2 and Order Approving on an Accelerated Basis a Proposed Rule Change, as Modified by Amendment No. 2, to List and Trade Shares of the GraniteShares Platinum Trust under NYSE Arca Rule 8.201–E); 81918 (October 23, 2017), 82 FR 49884 (October 27, 2017) (SR–NYSEArca–2017–98) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, to List and Trade Shares of The Gold Trust under NYSE Arca Rule 8.201–E); 80840 (June 1, 2017), 82 FR 26534 (June 7, 2017) (SR–NYSEArca–2017–33) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 2 Thereto, to List and Trade Shares of the Euro Gold Trust,

The Registration Statement stated that the custodian of the Trust is the Gold Corporation. The Exchange proposes to change this representation to state that the Trust's custodian will be JPMorgan Chase Bank, N.A. (''Custodian''), which will take on all of the responsibilities of the Gold Corporation (in its role as custodian).[11]

Change to Taking Delivery of Physical Gold by Investors

The Prior Releases described procedures permitting an investor to take delivery of Physical Gold in exchange for its shares, provided the investor follows certain procedures set out in the Registration Statement. In connection with the replacement of the custodian of the Trust, the Exchange proposes to eliminate an investor's ability to take delivery of Physical Gold. Therefore, all references in the Prior Releases regarding investors taking delivery of Physical Gold will no longer be in effect.[12] The Trust's investment objective is for the Shares to reflect the performance of the price of gold less the expenses of the Trust's operations. Further, Goldman Sachs Asset Management, L.P. represents that the option to take delivery of Physical Gold has been utilized only 12 times since the inception of the Trust. Given the limited use of this feature and the fact that investors have been notified through the 8–K that this feature will be removed, this change will not impact investors' ability to invest in a product that reflects the performance of the price of gold less the expenses of the Trust's operations. The Exchange notes that, except as described in this proposed rule change, procedures relating to creation and redemption of Shares as applied to Authorized Participants, as described in the Prior Releases, will remain unchanged.[13]

Change to Representation Regarding the Government Guarantee

The Prior Notice referred to a Government Guarantee provided by the State of Western Australia[14] and stated that the Government Guarantee applies to all gold held by the Custodian or sub-custodian, whether in the Trust Allocated Metal Account, the Trust Unallocated Metal Account, the ''GC Metal Account'' or in a Customer Account, for the benefit of the Trust or an investor who is the Gold Corporation's direct customer. The Government Guarantee applies only to Physical Gold held in The Perth Mint's vaults.

As the Custodian is not affiliated with the State of Western Australia, the Custodian intends to substitute the Government Guarantee with insurance on the Physical Gold held by the Custodian or a sub-custodian. The Custodian has represented that it will maintain adequate insurance from reputable and solvent insurers of international standing that is customary with other single-asset commodity-based Exchange Traded Products. Moreover, the costs of insuring the Physical Gold held by the Custodian or a sub-custodian will be assumed by the Custodian and not the Trust directly. The Trust's expense ratio will not change as a result of the new Custodian being appointed. Accordingly, the Exchange proposes to change this representation to state that the Government Guarantee referenced in the Prior Releases is eliminated. Because the Custodian intends to provide insurance to the Trust for the Physical Gold held by the Custodian or a sub-custodian, the removal of the Government Guarantee will not impact investors' ability to invest in the Shares.

Change to Representation Regarding Delivery of Required Deposits

The First Prior Notice stated that an Authorized Participant who places a purchase order is responsible for crediting the Trust Unallocated Metal Account with the required gold deposit amount by 9:00 a.m. London time on the third business day following the purchase order date. The Exchange proposes to change the above reference from 9:00 a.m. London time to 8:00 a.m. London time.

In addition, in connection with information regarding the required gold deposit, the Exchange proposes that the Sponsor shall publish, or shall designate another person to publish, for each business day, the ''Basket Gold Amount''.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[15] that an exchange have rules that are 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, in general, to protect investors and the public interest.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

With respect to the proposed elimination of an investor's ability to take delivery of Physical Gold, the Exchange believes that, given the limited use of this feature, as noted above, and the fact that investors have been notified through the 8–K that this feature will be removed, this change will not impact investors' ability to invest in the Shares. The Exchange notes that the Commission has previously approved Exchange listing and trading of shares of gold trusts under NYSE Arca Rule 8.201–E without the ability of individual investors to receive Physical Gold from a trust outside the redemption process utilized

Pound Gold Trust, and the Yen Gold Trust under NYSE Arca Equities Rule 8.201).

[11] In regard to the role of the Custodian, footnote 8 of the First Prior Notice stated the following: ''As Custodian of the Trust's gold bullion, Gold Corporation will be responsible for the safekeeping of the Trust's gold and supplying inventory information to the Trustee and the Sponsors. The Custodian will also be responsible for facilitating the transfer of gold in and out of the Trust and facilitating the shipment of Physical Gold to Delivery Applicants.'' The Exchange proposes to change this representation to the following: ''As Custodian of the Trust's gold bullion, the Custodian will be responsible for the safekeeping of the Trust's gold and supplying inventory information to the Trustee and the Sponsor.'' A prospectus to the Registration Statement will be filed at the closing of the Sponsorship Transfer Agreement incorporating the changes listed herein.

[12] Procedures regarding delivery of Physical Gold to investors are described in the following sections of the First Prior Notice: ''Permitting Investors to Take Delivery of Physical Gold,'' ''Taking Delivery of Physical Gold—Delivery Applicants'' and ''Delivery Application''; and in the following section of the Second Prior Release: ''Changes to Representations Regarding Delivery Applicants.''

[13] The Exchange notes that the Commission has previously approved Exchange listing and trading of shares of gold trusts under NYSE Arca Rule 8.201–E without the ability of individual investors to receive Physical Gold from a trust outside the redemption process utilized by Authorized Participants. *See e.g.,* Securities Exchange Act Release Nos. 81077 (July 5, 2017), 82 FR 32024 (July 11, 2017) (SR–NYSEArca-2017–55) (order approving listing and trading shares of the GraniteShares Gold Trust under NYSE Arca Equities Rule 8.201; 75918 (December 9, 2016), 81 FR 90876 (December 15, 2016) (SR–NYSEArca–2016–84) (order approving listing and trading of shares of the Long Dollar Gold Trust Under NYSE Arca Equities Rule 8.201); 80840 (June 1, 2017), 82 FR 26534 (June 7, 2017) (SR–NYSEArca–2017–33) (order approving listing and trading of shares of the Euro Gold Trust, Pound Gold Trust, and the Yen Gold Trust Under NYSE Arca Equities Rule 8.201).

[14] *See* note 29 of the Prior Notice, which stated that the Gold Corporation, doing business as the Perth Mint, is a Western Australian Government owned statutory body corporate established by the Gold Corporation Act 1987 (Western Australia) (the ''WA Act''). The Government Guarantee provided by the State of Western Australia pursuant to Section 22 of the WA Act provides (among other things) that the payment of the cash equivalent of gold due, payable and deliverable by the Custodian under the WA Act is guaranteed by the Treasurer of Western Australia, in the name and on behalf of the Crown in the right of the State of Western Australia.

[15] 15 U.S.C. 78f(b)(5).

by Authorized Participants.[16] Except as described in this proposed rule change, procedures relating to creation and redemption of Shares as applied to Authorized Participants, as described in the Prior Releases, will remain unchanged.

With respect to the proposed elimination of the Government Guarantee as referenced above, because the Custodian intends to provide insurance to the Trust for the Physical Gold held by the Custodian or a sub-custodian, the removal of the Government Guarantee will not impact investors' ability to invest in a product that reflects the performance of the price of gold less the expenses of the Trust's operations.

The Exchange represents that the proposed changes described above are consistent with the Trust's investment objective, and will further assist the Sponsor to achieve such investment objective. Except for the changes noted above, all other representations made in the Prior Releases remain unchanged.

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 believes the proposed rule changes, because of the removal of the ability for investors to take delivery of Physical Gold, like other gold trusts listed under NYSE Arca Rule 8.201–E,[17] and the reduction in certain time frames, regarding delivery of required deposits and other redemption procedures, will enhance competition among issues of gold-based Commodity-Based Trust Shares.

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

Because the foregoing 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[18] and Rule 19b–4(f)(6) thereunder.[19]

A proposed rule change filed under Rule 19b–4(f)(6)[20] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b-4(f)(6)(iii)[21] permits the Commission to 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 so that the proposed rule change may become effective and operative immediately upon filing. The Exchange states that the proposed changes will not adversely impact investors and will permit the Trust to promptly implement the efficiencies associated with the proposed operational and administrative changes described in the 8–K. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[22]

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–NYSEArca–2020–100 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–NYSEArca-2020–100. 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 offices 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– NYSEArca–2020–100, and should be submitted on or before December 28, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

J. Matthew DeLes Dernier,

Assistant Secretary.

[FR Doc. 2020–26674 Filed 12–3–20; 8:45 am]

BILLING CODE 8011–01–P

[16] *See* note 13, *supra*.

[17] Id.

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 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.

[20] 17 CFR 240.19b–4(f)(6).

[21] 17 CFR 240.19b–4(f)(6)(iii).

[22] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* also 15 U.S.C. 78c(f).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90535; File No. SR–FINRA–2020–024]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1 To Delete the FINRA Order Audit Trail System (OATS)

November 30, 2020.

I. Introduction

On August 14, 2020, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] proposed rule changes to delete the Order Audit Trail System (''OATS'') rules in the FINRA Rule 7400 Series and FINRA Rule 4554 (the ''OATS Rules'') once members are effectively reporting to the Consolidated Audit Trail (''CAT''). On September 1, 2020, the proposed rule change was published for comment in the **Federal Register.**[3] On October 8, 2020, the Commission extended the time period for Commission action on the proposed rule change to November 30, 2020.[4] The Commission received three comment letters on the Notice.[5] On October 29, 2020, FINRA responded to the comment letters,[6] and filed Amendment No. 1 to the proposed rule change (''Amendment No. 1''). The Commission is publishing this notice to solicit comments on Amendment No. 1 to the proposed rule change from interested parties and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Background

Pursuant to Section 11A of the Exchange Act [7] and Rule 608 of Regulation NMS thereunder,[8] FINRA and other self-regulatory organizations filed with the Commission a National Market System Plan Governing the Consolidated Audit Trail (the ''CAT NMS Plan'' or ''Plan'') [9] to comply with Rule 613 of Regulation NMS under the Exchange Act.[10] The Plan was published for comment in the **Federal Register** on May 17, 2016,[11] and approved by the Commission, as modified, on November 15, 2016.[12] On March 15, 2017, the Commission approved rule change proposals submitted by the by all the national securities exchanges and association that are party to the CAT NMS Plan (''Participants'') that implement provisions of the CAT NMS Plan applicable to their members (the ''CAT Compliance Rules'').[13]

The CAT NMS Plan is designed to create, implement, and maintain a consolidated audit trail that will capture in a single consolidated data source customer and order event information for orders in NMS Securities and OTC Equity Securities (together, ''CAT-Eligible Securities''), across all markets, from the time of order inception through routing, cancellation, modification, or execution. Section C.9 of Appendix C to the Plan requires each Participant to ''file with the SEC the relevant rule change filing to eliminate or modify its duplicative rules within six (6) months of the SEC's approval of the CAT NMS Plan'' and states that ''the elimination of such rules and the retirement of such systems [will] be effective at such time as CAT Data meets minimum standards of accuracy and reliability.'' FINRA submitted a proposed rule change that was substantively similar to the instant filing on May 15, 2017.[14] FINRA subsequently withdrew the filing on January 12, 2018.[15]

Section C.9 of Appendix C to the Plan also requires these rule filings to discuss the following:

(i) Specific accuracy and reliability standards that will determine when duplicative systems will be retired, including, but not limited to, whether the attainment of a certain Error Rate should determine when a system duplicative of the CAT can be retired;

(ii) whether the availability of certain data from Small Industry Members would facilitate a more expeditious retirement of duplicative systems; and

(iii) whether individual Industry Members can be exempted from reporting to duplicative systems once their CAT reporting meets specified accuracy and reliability standards, including, but not limited to, ways in which establishing cross-system regulatory functionality or integrating data from existing systems and the CAT would facilitate such Individual Industry Member exemptions.[16]

In response to these requirements, FINRA submitted the instant filing (the ''Proposal''), which is described below.

III. Description of the Proposed Rule Changes

As required by the CAT NMS Plan, the Proposal discusses: (1) The specific standards that will govern when OATS will be eliminated; (2) whether the availability of data from Small Industry Members would facilitate duplicative systems retirement; and (3) the feasibility of granting exemptions from reporting to duplicative systems to individual Industry Members whose CAT reporting meets certain accuracy and reliability thresholds.

A. Specific Accuracy and Reliability Standards

1. OATS

The OATS rules require certain FINRA members to report a variety of data regarding transactions in OTC equity securities and NMS stocks to OATS on a daily basis.[17] In the proposal, FINRA proposes to delete its OATS rules from its rulebook once CAT Data achieves certain pre- and post-correction error rates and certain qualitative criteria have been met.

FINRA stated that it believes that relevant error rates are the primary, but not the sole, metric by which to determine the CAT's accuracy and reliability and will serve as the baseline

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89679 (August 26, 2020), 85 FR 54461 (the ''Notice'').

[4] *See* Securities Exchange Act Release No. 90129, 85 FR 65113 (October 14, 2020).

[5] *See* Letters from William J. Leahey, Head of Regulatory Compliance, Refinitiv, to Vanessa Countryman, Secretary, Commission, dated September 22, 2020 (''Refinitiv Letter''); Howard Meyerson, Managing Director, Financial Information Forum, to Vanessa Countryman, Secretary, Commission, dated September 22, 2020 (''FIF Letter''); Ellen Greene, Managing Director, Equity & Options Market Structure, to Vanessa Countryman, Secretary, Commission, dated September 24, 2020.

[6] *See* Letter from Lisa C. Horrigan, Associate General Counsel, FINRA, to Vanessa Countryman, Secretary, Commission, dated October 29, 2020 (''Response Letter''). In Amendment No. 1, FINRA proposes to modify the proposal to provide that it will calculate the match rate in the aggregate across all equity exchanges instead of calculating the equity exchange match rate on a per exchange basis.

[7] 15 U.S.C. 78k–1.

[8] 17 CFR 242.608.

[9] *See* Letter from Participants to Brent J. Fields, Secretary, Commission, dated February 8, 2016. Prior versions of the CAT NMS Plan were submitted to the Commission on September 30, 2014; February 27, 2015; and December 23, 2015.

[10] 17 CFR 242.613.

[11] Securities Exchange Act Release No. 77724 (April 27, 2016), 81 FR 30614 (May 17, 2016).

[12] Securities Exchange Act Release No. 79318 (November 15, 2016), 81 FR 84696 (November 23, 2016) (''CAT Approval Order'').

[13] Securities Exchange Act Release Nos. 80255 (March 15, 2017), 82 FR 14563 (March 21, 2017); 80256 (March 15, 2017), 82 FR 14526 (March 21, 2017).

[14] *See* Securities Exchange Act 80783 (May 26, 2017), 82 FR 25423 (June 1, 2017)(SR–FINRA–2017–13).

[15] *See* Securities Exchange Act Release No. 82524 (January 17, 2018), 83 FR 3230 (January 23, 2018).

[16] *See id.*

[17] *See* FINRA Rule 7400.

requirement needed for OATS to be retired.[18] FINRA stated that the Participants established an initial Error Rate, as defined in the Plan, of 5% on initially submitted data (*i.e.,* data as submitted by a CAT Reporter before any required corrections are performed).[19] The Participants based this Error Rate on their consideration of ''current and historical OATS Error Rates, the magnitude of new reporting requirements on the CAT Reporters and the fact that many CAT Reporters may have never been obligated to report data to an audit trail.'' [20]

In the Proposal, FINRA expressed agreement with the Participants' conclusion that a 5% pre-correction threshold ''strikes the balance of adapting to a new reporting regime, while ensuring that the data provided to regulators will be capable of being used to conduct surveillance and market reconstruction, as well as having a sufficient level of accuracy to facilitate the retirement of existing regulatory reports and systems where possible.'' [21] However, FINRA believed that, when assessing the accuracy and reliability of the data for the purposes of retiring OATS, the error thresholds should be measured in more granular ways and should also include minimum error rates of post-correction data, which represents the data most likely to be used by FINRA to conduct surveillance. Although FINRA is proposing to measure the appropriate error rates in the aggregate rather than firm-by-firm, FINRA expressed the belief that the error rates for equity securities should be measured separately from options since options orders are not currently reported regularly or included in OATS.[22]

FINRA also proposes that, before OATS is retired, the CAT would generally need to achieve a sustained error rate for Industry Member reporting in each of the categories below:

• *Rejection Rates and Data Validations.* FINRA has reviewed the data validations for the CAT, which are set forth in the Industry Member Technical Specifications published by the Plan Processor,[23] and confirmed that they are substantially similar to OATS. While not required to be designed the same as OATS, data validations must be functionally equivalent to OATS in accordance with the CAT NMS Plan (*i.e.,* the same types of basic data validations must be performed by the Plan Processor to comply with the CAT NMS Plan requirements). Appendix D of the Plan, for example, requires that certain file validations [24] and syntax and context checks be performed on all submitted records.[25] If a record does not pass these basic data validations, it must be rejected and returned to the CAT Reporter to be corrected and resubmitted.[26] The Plan also requires the Plan Processor to provide daily statistics on rejection rates after the data has been processed, including the number of files rejected and accepted, the number of order events accepted and rejected, and the number of each type of report rejected.[27] FINRA is proposing that, over the 180-day period, aggregate rejection rates (measured separately for equities and options) must be no more than 5% pre-correction or 2% post-correction across all CAT Reporters.[28]

• *Intra-Firm Linkages.* The Plan requires that ''the Plan Processor must be able to link all related order events from all CAT Reporters involved in the lifecycle of an order.'' [29] At a minimum, this requirement includes the creation of an order lifecycle between ''[a]ll order events handled within an individual CAT Reporter, including orders routed to internal desks or departments with different functions (*e.g.,* an internal ATS).'' [30] FINRA is proposing that aggregate intra-firm linkage rates across all Industry Member Reporters must be at least 95% pre-correction and 98% post-correction.

• *Inter-Firm Linkages.* The order linkage requirements in the Plan also require that the Plan Processor be able to create the lifecycle between orders routed between broker-dealers.[31] FINRA is proposing that at least a 95% pre-correction and 98% post-correction aggregate match rate be achieved for orders routed between two Industry Member Reporters.[32]

• *Order Linkage Rates.* In addition to creating linkages within and between broker-dealers, the Plan also includes requirements that the Plan Processor be able to create lifecycles to link various pieces of related orders.[33] For example, the Plan requires linkages between customer orders and ''representative'' orders created in firm accounts for the purpose of facilitating a customer order, riskless principal orders, and orders worked through average price accounts.[34] Pursuant to the phased approach for Industry Member reporting certain of these order linkages will not be required in the initial phase of reporting (or ''Phase 2a''), which commenced on June 22, 2020.[35] FINRA is proposing that there be at least a 95% pre-correction and 98% post-correction linkage rate for orders that are required in Phase 2a.

While such linkages are not required in OATS today, FINRA believes that it is appropriate to evaluate them for purposes of retiring OATS. These linkages represent a significant enhancement to the data currently available in OATS and will enhance the quality of the equity audit trail. FINRA does not anticipate that the error rates for the Phase 2a representative order

[18] *See* Notice, *supra* note 3 at 54463.

[19] *See* CAT NMS Plan, Appendix B, Section A.3(b).

[20] *See* CAT NMS Plan, Appendix C, Section A.3(b).

[21] *Id.*

[22] *See* Notice, *supra* note 3 at 54463.

[23] *See, e.g.,* Industry Member Technical Specifications (2a/2b) version 2.2.1 r6, dated June 22, 2020, available at *www.catnmsplan.com/sites/default/files/2020-06/CAT_Reporting_Technical_Specifications_for_Industry%20Members_v2.2.1r6_CLEAN.pdf.*

[24] *See* CAT NMS Plan, Appendix D, Section 7.2. The Plan requires the Plan Processor to confirm that file transmission and receipt are in the correct formats, including validation of header and trailers on the submitted report, confirmation of a valid SRO-Assigned Market Participant Identifier, and verification of the number of records in the file. *Id.*

[25] *See id.* The Plan provides that syntax and context checks would include format checks (*i.e.,* that data is entered in the specified format); data type checks (*i.e.,* that the data type of each attribute conforms to the specifications); consistency checks (*i.e.,* that all attributes for a record of a specified type are consistent); range/logic checks (*i.e.,* that each attribute for every record has a value within specified limits and the values provided are associated with the event type they represent); data validity checks (*i.e.,* that each attribute for every record has an acceptable value); completeness checks (*i.e.,* that each mandatory attribute for every record is not null); and timeliness checks (*i.e.,* that the records were submitted within the submission timelines). *Id.*

[26] *See id.*

[27] *See id.*

[28] CAT NMS Plan, Appendix C, Section A.3(b), at n. 102. FINRA stated that while error rates after reprocessing of error corrections are ultimately expected to be de minimis for the CAT, it does not believe that post-correction errors need to be de minimis before OATS can be retired and is not suggesting, with this proposal, that 2% would meet the ultimate objective of de minimis error rates for CAT. In other words, the Proposal does not change the standard under the CAT NMS Plan that post-correction errors must be de minimis. *See* Notice, *supra* note 3 at n. 24.

[29] CAT NMS Plan, Appendix D, Section 3.

[30] *Id.*

[31] *Id.*

[32] This assumes linkage statistics will include both unlinked route reports and new orders where no related route report could be found.

[33] *See* CAT NMS Plan, Appendix D, Section 3.

[34] *See id.*

[35] *See* CAT Reporting Timelines at *www.catnmsplan.com/timelines/. See also* Securities Exchange Act Release No. 88702 (April 20, 2020), 85 FR 23075 (April 24, 2020) (Order Granting Conditional Exemptive Relief from Sections 6.4, 6.7(a)(v) and 6.7(a)(vi) of the CAT NMS Plan) (''Phased Industry Member Reporting Exemptive Order'') and FINRA Rule 6895. Linkages for representative order scenarios involving agency average price trades, net trades and aggregated orders will not be required until the third phase of reporting (or ''Phase 2c'') is implemented in April 2021; such linkages are not required in OATS today.

linkages in CAT would be significantly higher than the order linkages available in OATS today. Nonetheless, in evaluating whether the standards for OATS retirement have been met, FINRA has stated that it will take into consideration if the error rates for the Phase 2a representative order linkages have a significant negative impact on the overall error rates for order linkages.

• *Exchange and TRF/ORF Match Rates.* The Plan requires that an order lifecycle be created to link ''[o]rders routed from broker-dealers to exchanges'' and ''[e]xecuted orders and trade reports.'' [36] FINRA is proposing at least a 95% pre-correction and 98% post-correction aggregate match rate across all equity exchange for orders routed from Industry Members to an exchange and, for over-the-counter executions, the same match rate for orders linked to trade reports.[37]

FINRA has stated that it intends to commence its review of CAT data and error rates based on Phase 2a data and linkages, which would replicate the data in OATS today, and will not wait for implementation of Phase 2c reporting (and the attendant linkages) to do so. Large Industry Members and Small Industry Members that currently are reporting to OATS (''Small Industry OATS Reporters'') are required to submit data to the CAT for these same events and scenarios during Phase 2a. Accordingly, FINRA believes that Phase 2a Industry Member Data is the most relevant for OATS retirement purposes. FINRA anticipates that it will retire OATS based solely on Phase 2a reporting, assuming the threshold pre- and post-correction error rates are achieved and FINRA's use of the data confirms that the data is accurate and reliable, as discussed below.

Once these error rate thresholds are met, FINRA has stated that it must also evaluate and confirm through incorporation of CAT Data into its automated surveillance program that the data is accurate and reliable.[38] Thus, in addition to the maximum error rates and matching thresholds proposed above, FINRA's proposal requires that use of CAT Data must confirm that (i) there are no material issues that have not been corrected (*e.g.,* delays in the processing of data, issues with query functions, etc.), (ii) the CAT includes all data necessary to allow FINRA to continue to meet its surveillance obligations and (iii) the Plan Processor is sufficiently meeting its obligations under the CAT NMS Plan relating to the reporting and linkage of Phase 2a Industry Member Data. FINRA believes that any errors in the CAT Data may manifest themselves only after surveillance patterns and other queries have been run. Thus, FINRA believes that while error rate thresholds may be met over a 180-day period, additional time may be required to reliably establish that usage of the CAT has not revealed material issues that have not been corrected and allow contextual analysis of the data to take place to uncover errors in reporting or processing that may not be apparent from more standardized data processes.

In order to alert members of the status of the OATS Rules, if the Commission approves the proposed rule change, FINRA is proposing to add introductory language to Rule 4554 and the Rule 7400 Series that will state that the SEC has approved a proposed rule change (SR–FINRA–2020–024) to remove Rule 4554 and the Rule 7400 Series from the FINRA rulebook; however, by its terms, SR–FINRA–2020–024 will not be implemented until FINRA has determined that the CAT has achieved a level of accuracy and reliability sufficient to replace OATS. FINRA has stated that once it has determined that such standards have been met, FINRA will file for immediate effectiveness a rule filing setting forth the basis for its determination and will publish a *Regulatory Notice* announcing the implementation date of SR–FINRA–2020–024.

2. Small Industry Member Data Availability

The second issue the Plan requires the proposed rule change to address is ''whether the availability of certain data from Small Industry Members two years after the Effective Date would facilitate a more expeditious retirement of duplicative systems.'' [39] FINRA believes that there is no effective way to retire OATS until all current OATS reporters are reporting to the CAT. Pursuant to the phased reporting approach, Small Industry OATS Reporters and Large Industry Members were required to begin reporting to the CAT on the same date, June 22, 2020. Thus, at this time, all current OATS reporters are required to report to the CAT.[40] Small Industry Members that are not currently required to record and report information to OATS are required to begin reporting to the CAT in December 2021.[41]

3. Individual Industry Member Exemptions

The final issue the Plan requires the proposed rule change to address is ''whether individual Industry Members can be exempted from reporting to duplicative systems once their CAT reporting meets specified accuracy and reliability standards, including, but not limited to, ways in which establishing cross-system regulatory functionality or integrating data from existing systems and the CAT would facilitate such Individual Industry Member exemptions.'' [42]

FINRA has stated that it believes that a single cut-over from OATS to CAT is highly preferable to a firm-by-firm approach and is not proposing to exempt members from the OATS requirements on a firm-by-firm basis.[43] FINRA explained that the primary benefit to a firm-by-firm exemptive approach would be to reduce the amount of time an individual firm is required to report to a legacy system (*e.g.,* OATS) if it is also accurately and reliably reporting to the CAT. FINRA believes that the overall accuracy and reliability thresholds for the CAT described above would need to be met under any conditions before firms could stop reporting to OATS. In addition, a firm-by-firm approach would require that OATS and CAT data be combined and integrated in order for FINRA to conduct surveillance in accordance with SEC rules and SRO obligations. Moreover, as discussed above, Small Industry OATS Reporters are required to report to the CAT on the same timeframe as all other OATS Reporters (*i.e.,* Large Industry Members). Thus, FINRA believes there is no need to exempt members from OATS requirements on a firm-by-firm basis.

IV. Discussion and Commission Findings

After carefully considering the Proposal, the comments submitted, and FINRA's response to the comments, the Commission finds that the proposed rule change, as modified by Amendment No., 1 is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges and associations.[44] Specifically, the

[36] *Id.*

[37] *See* Amendment No. 1, *supra* note 6.

[38] For example, FINRA will need to transition all or substantially all of its automated surveillance patterns to CAT Data in order to evaluate the accuracy and reliability of the data.

[39] *See* CAT NMS Plan, Appendix C, Section C.9.

[40] The 180-day timeframes discussed above with respect to usage of the data and calculation of error rates will apply to data reported to the CAT by Small Industry OATS Reporters.

[41] *See supra* note 36.

[42] *See* CAT NMS Plan, Appendix C, Section C.9.

[43] *See* Notice, *supra* note 3, at 54465.

[44] In approving these proposed rule changes, the Commission has considered the proposed rules'

Continued

Commission finds that the Proposal is consistent with Section 15A(b)(6) of the Act,[45] which requires, among other things, that the rules of an association be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and are not designed to permit unfair discrimination between customers, issuers, brokers or dealers. In addition, the Commission finds the Proposal is consistent with Section 15A(b)(9) of the Act,[46] which requires that the rules of an association not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Commission also finds that the proposed rule change is consistent with Section 11A of the Act,[47] and the CAT NMS Plan. Section 11A of the Act directs the Commission, with due regard for the public interest, the protection of investors, and the maintenance of fair and orderly markets, to use its authority to facilitate the establishment of a national market system for securities, including by authorizing or requiring SROs to act jointly to plan, develop, operate, or regulate a national market system. As discussed above, the Plan requires the proposal to discuss the specific accuracy and reliability standards that would determine when duplicative systems would be retired, whether the availability of certain data from Small Industry Members would facilitate a more expeditious retirement of duplicative systems, and whether individual Industry Members could be exempted from reporting to duplicative systems once their CAT reporting meets specified accuracy and reliability standards.[48] Accordingly, FINRA filed the Proposal to indicate when the OATS Rules would be eliminated once CAT is sufficiently accurate and reliable and to explain how they intend to assess CAT's accuracy and reliability. As discussed below, the Commission believes that the Proposal is consistent with the above-noted provisions of the CAT NMS Plan and consistent with the Act because it is reasonably designed to assist the SROs in meeting their regulatory obligations pursuant to Rule 613 and the Plan.

The Commission finds that FINRA's proposal to delete its OATS rules is consistent with the Act. While OATS has provided an important resource for surveillance of the OTC market for equity securities, CAT is designed to be a more robust tool for market surveillance. Unlike OATS, the CAT will include order and transaction information from the Exchanges and will enable regulators to trace the complete life cycle of every order, regardless of whether it is routed or executed OTC or on an exchange.

FINRA's proposed approach to the timing of retiring OATS is appropriate. Three commenters stated the need for the ''urgent decommissioning of OATS'',[49] and for the retirement of OATS in ''an efficient and timely manner'' [50] and on an ''expedited basis'' [51] to address the current duplication of firm resources. In its Response Letter, FINRA stated that it understands the technology costs and resources firms have dedicated and continue to dedicate to OATS, and that FINRA is committed to retiring OATS as efficiently and expeditiously as possible. The commenters also believed that OATS could be retired prior to the commencement of Phase 2c reporting on April 26, 2021. They expressed concern that Phase 2c error rate reporting would negatively impact the timing for the retirement of OATS.[52] However, the retirement of OATS is independent of Phase 2c reporting. The earliest OATS can be retired is April 26, 2021 because error rate thresholds must be met over a 180-day period. In addition, as discussed in greater detail below, Phase 2c error rates are not part of the OATS retirement error rate calculation and therefore should not delay the retirement of OATS. In finding that the proposed timing for retiring OATS, after commencement of Phase 2c reporting on April 26, 2021, is consistent with the Act, the Commission considered FINRA's representation that it will not take Phase 2c error rates into account in determining whether the proposed standards for the retirement of OATS have been met. Thus, the Commission believes that the commencement of Phase 2c reporting does not impact the timing of OATS retirement.

All three commenters commented on FINRA's proposal to evaluate and confirm, through incorporation of CAT Data into its automated surveillance program, that CAT Data is accurate and reliable.[53] One of these commenters argued that the process for incorporating CAT Data into FINRA's surveillance program should begin as soon as possible and asked FINRA to clarify that it will not wait for industry reporting to achieve the applicable error rates for 180 days before beginning to test its systems.[54] Another commenter stated that while it agrees with FINRA's goal of operationalizing CAT Data in its automated surveillances with the confidence necessary for FINRA to eliminate OATS, this is dependent on factors outside the control of Industry Members.[55] In addition, the third stated that the ''open-ended nature'' of the non-error-rate conditions should not extend the retirement of OATS beyond the 180-day period.[56] The Commission believes that the proposed conditions relating to FINRA's use of the CAT Data are consistent with the CAT NMS Plan. The CAT NMS Plan provides that FINRA must be able to verify that the data is of ''sufficient quality for surveillance purposes.''

In any event, FINRA stated that it has already begun the process of transitioning its automated surveillance patterns and testing the CAT Data, addressing commenters' concerns that FINRA is not waiting for industry reporting to achieve the applicable error rates for a 180-day period before commencing this process. However, as FINRA explained, the errors in the CAT Data may not be apparent until surveillance patterns and other queries have been run.[57] Error rate thresholds may be met over a 180-day period, however, additional time may be required to reliably allow contextual analysis of the data to take place to uncover errors in reporting or processing that may not be apparent from more standardized data validation processes. For these reasons, the Commission concludes that FINRA's proposal to evaluate and confirm that CAT Data is accurate and reliable is reasonable.

The Commission concludes that FINRA's proposed approach to review CAT data and error rates to determine if the OATS Rules can be deleted based on Phase 2a Industry Member data and linkages is appropriate as this is the data reported in OATS today, and thus is the most relevant for determining if OATS

impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[45] 15 U.S.C. 78o–3(b)(6).

[46] 15 U.S.C. 78o–3(b)(9).

[47] 15 U.S.C. 78k–1.

[48] *See* CAT NMS Plan, Appendix C, Section C.9. *See* Phased Industry Member Reporting Exemptive Order, *supra* note 34.

[49] *See* Refinitiv Letter, *supra* note 5.

[50] *See* SIFMA Letter, *supra* note 5.

[51] *See* FIF Letter, *supra* note 5.

[52] *See* FIF Letter, Refinitiv Letter, and SIFMA Letter, *supra* note 5.

[53] *See* FIF Letter, Refinitiv Letter, and SIFMA Letter, *supra* note 5.

[54] *See* SIFMA Letter, *supra* note 5.

[55] *See* Refinitiv Letter, *supra* note 5.

[56] *See* FIF Letter, *supra* note 5.

[57] *See* Response Letter, *supra* note 6, at 4.

should be retired.[58] Two commenters objected to FINRA including error rates for Phase 2a representative order linkages, arguing that such linkages are not required in OATS and therefore should be not considered in determining whether OATS can be retired.[59] The representative order linkages required in Phase 2a are ''simple'' linkages,[60] and do not include more complex representative order scenarios, such as those involving agency average price trades, net trades and aggregated orders, which will not be required until Phase 2c. Statistics provided by FINRA CAT show that firms are performing these linkages with error rates well under those FINRA is proposing to require for retirement of OATS.[61] Based on these statistics, the Phase 2a representative order linkages should not significantly impact linkage error rates for OATS retirement purposes.[62] In addition, in evaluating whether the standards for OATS retirement have been met, FINRA will evaluate whether the error rate is the result of unlinked representative orders to create an apples-to-apples comparison to OATS.[63]

FINRA has committed to retiring OATS as soon as reasonably practicable,[64] and has stated that if all other proposed criteria have been met, it does not anticipate delaying OATS retirement based on Phase 2a representative order linkage error rates alone.[65] The Commission believes that including error rates for Phase 2a representative order linkages is reasonable, as they will be included by FINRA's automated surveillance program and are not impacting error rates to date.[66] Actual data provided by FINRA CAT is consistent with FINRA's representation in its Response Letter that it is unlikely that the error rates for the Phase 2a representative order linkages in CAT will be significantly higher than the order linkages available in OATS today,[67] and FINRA does not anticipate delaying OATS retirement based solely on Phase 2a representative order linkage error rates.[68]

The Commission also finds that FINRA's proposed framework for assessing the accuracy and reliability of CAT Data for purposes of retiring OATS—including the ''single cut-over'' approach; and the scope, commencement, timeframe, and methodology of the assessment—is consistent with the Act. The Plan states that the elimination or modification of the SROs' duplicative rules and the retirement of the related systems will be ''effective at such time as CAT Data meets minimum standards of accuracy and reliability.'' [69] ''CAT Data'' is defined broadly [70] and includes customer information and order and transaction records pertaining to NMS stocks, OTC Equity Securities, and listed options submitted by both Participants and Industry Members. The Commission finds that the assessment mechanism proposed by FINRA is consistent with both the Act and the CAT NMS Plan, because it is reasonably designed to ensure that, before OATS is retired and OATS reporting requirements are eliminated, CAT is operating with sufficient accuracy and reliability for regulatory purposes, including by assessing whether compliance with key requirements of the CAT NMS Plan has been attained.

Although FINRA generally intends to limit its assessment of error rates to Industry Member Data and to focus its assessment on fields and securities that are currently in OATS, some information that is outside the scope of OATS could be relevant to the consideration of the overall accuracy and reliability of the CAT and the performance of the Plan Processor. The Commission believes that while consideration must be given to the overall accuracy and reliability of CAT Data more broadly, it is appropriate for FINRA to focus their assessment of whether CAT is performing with a sufficient degree of accuracy and reliability to permit OATS retirement on data related to OATS-eligible securities by the same types of entities (*i.e.,* broker-dealers) that are required to submit OATS reports. An assessment of the quality of broker-dealer reporting to CAT could be skewed by consideration of Participant reporting, particularly considering that Participants are required to report one year sooner than Industry Members and, all things being equal, can be expected to attain higher level of accuracy before Industry Members. Furthermore, focusing on Industry Member records will help identify any issues specific to this class of CAT Reporters and facilitate quicker improvements. This in turn could provide regulators with better oversight capability more quickly and help minimize the costs associated with duplicative reporting.

In addition, the Commission believes that FINRA's assessment of the data quality of specific categories of errors—*i.e.,* rejection rates, intra-firm linkages, inter-firm linkages, order linkage rates, exchange and TRF/ORF match rates—are appropriate. The categories identified by FINRA are categories of errors calculated by OATS today and reflect key aspects of data quality that affect the ability of regulators to effectively access and use CAT Data to perform their regulatory functions. Thus, Commission believes it is reasonable for FINRA to examine these aspects of the data to confirm that they are exhibiting accuracy levels consistent with the required pre- and post-correction accuracy levels of CAT Data overall. In particular one of the significant limitations of existing audit trail systems is the deficiency of linkages between the various events in the order life cycle—and the lack of linkage to specific customers—which results in regulators attempting to link these events together themselves from various sources through *ad hoc* and cumbersome processes that can introduce errors.[71] Therefore, the Commission concludes that it is appropriate for FINRA's assessment to include various aspects of order and transaction linkages.

Moreover, the Commission concludes that it is appropriate for FINRA to allow retirement of OATS only when the 5% pre-correction and 2% post-correction thresholds are met in each category. The 5% pre-correction threshold is the same as the initial maximum pre-correction

[58] All Industry Members that currently are reporting to OATS are required to the submit data to the CAT during Phase 2a. *See* Phased Industry Member Reporting Exemptive Order, *supra* note 35.

[59] *See* Refinitiv Letter and SIFMA Letter, *supra* note 5.

[60] In Phase 2a, linkage is required between the representative street side order and the order being represented when the representative order was originated specifically to represent a single order (received either from a customer or another broker-dealer) and there is: (1) An existing direct electronic link in the firm's system between the order being represented and the representative order, and (2) any resulting executions are immediately and automatically applied to the represented order in the firm's system. *See* Response Letter, *supra* note 6, at n. 7.

[61] *See https://catnmsplan.com/sites/default/files/2020-11/11.19.20-Monthly-CAT-Implementation-Update.pdf,* at p. 5.

[62] *See* Response Letter, *supra* note 6, at 6.

[63] *Id.* at 7.

[64] *Id.* at 5.

[65] *Id.* at 6–7.

[66] *See supra* note 61.

[67] *Id.*

[68] *See* Response Letter, *supra* note 3, at 6–7.

[69] CAT NMS Plan, Appendix C, Section C.9.

[70] *See* CAT NMS Plan, Section 1.1.

[71] *See, e.g.,* CAT Approval Order, 81 FR at 84814–15 (''cross-market examinations require the cumbersome and time-consuming task of linking many different data sources . . . regulators that are determining whether rule violations have occurred will combine trading data from sources such as public feeds, SRO audit trails, EBS data, and trade blotters''); Securities Exchange Act Release No. 77724 (April 27, 2016), 81 FR 30614, 30685 (May 17, 2016) (notice of CAT NMS Plan) (''data is currently stored in multiple formats, is difficult to merge, and results in errors during the merging process'').

error rate set forth in the CAT NMS Plan, and the 2% post-correction threshold is a reasonable quantification of the ''*de minimis*'' post-correction error rate contemplated by the CAT NMS Plan for the purposes of OATS retirement.[72] Thus, the Commission believes it is reasonable to not require accuracy rates in CAT to equal or surpass the accuracy rates in OATS before allowing for OATS retirement.

The Commission also concludes that the calculation methodologies proposed by FINRA for these metrics—specifically that the inter-firm linkage quality metric will be measured in the aggregate across all Industry Members rather than on a per-firm basis and that post-correction error rates will be measured as the number of errors in a particular category divided by the total number of records received in that category—are appropriate as this is how the CAT NMS Plan defines the calculation of these error rates.[73] Further, the Commission concludes that FINRA's approach of measuring post-correction error rates at T+5 is appropriate, as this is consistent with the requirements of the CAT NMS Plan.[74] It is appropriate to apply the data processing cycles and standards set forth in the CAT NMS Plan—such as regulatory access to corrected data on T+5—rather than standards associated with OATS or other existing systems to ensure that FINRA CAT's surveillances are adequate based on the data that will be reported. An assessment of the adequacy of FINRA CAT's processing based on OATS' or other systems' standards would not provide assurance that these systems would be sufficient under the applicable CAT NMS Plan requirements.

In addition to these assessment criteria and error rates, under FINRA's proposal, it must be able to confirm that (1) usage over the assessment period has not revealed material issues that have not been corrected; (2) the CAT includes all data necessary to allow FINRA to continue to meet its surveillance obligations; and (3) the Plan Processor is sufficiently meeting all of its obligations under the CAT NMS Plan. One commenter argued that these qualitative factors, which they referred to as ''non-error-rate conditions,'' appear to go beyond the conditions set forth in the CAT NMS Plan, and they have concerns about the open-ended nature of the non-error-rate conditions.[75] The CAT NMS Plan requires that a system retirement proposal discuss ''specific accuracy and reliability standards that will determine when duplicative systems will be retired, including, *but not limited to,* whether the attainment of a certain Error Rate should determine when a system duplicative of CAT can be retired'' (emphasis added).[76] The Commission believes that the qualitative factors identified by FINRA in addition to quantitative metrics such as error rates are consistent with this requirement. For example, even if CAT Reporters are reporting accurate data to the Central Repository, as measured by error rates, regulators might not be able to use CAT as intended if the Plan Processor is not adequately performing its functions, such as linking reportable events together to create a complete order life cycle and providing access and querying functionality to regulators. The Commission therefore concludes that it is appropriate for FINRA to consider these qualitative factors.

The transparency regarding the assessment process and communication with Industry Members regarding any issues identified during that process will be beneficial. FINRA has committed to provide the industry with information and updates directly and through FINRA CAT regarding CAT implementation issues by holding periodic industry outreach events.[77] These opportunities for regular and ongoing feedback about any issues identified will facilitate the correction of such issues and reduce the potential for delays in systems retirement.

The Commission finds that FINRA's proposal with respect to the length of the assessment are consistent with the Act. Before a crucial regulatory tool such as OATS can be retired, it is prudent to ensure that error rates in the replacement audit trail system have reached stabile, consistent levels. FINRA has represented that, based on past experience, 180 days represents the minimum time needed to fully test the accuracy and reliability of trade and order data and system functionality to ensure that FINRA is able to carry out its surveillances and other regulatory functions without a loss of quality. The Commission concludes that a 180-day period strikes a reasonable balance between ensuring that high accuracy and reliability levels are sustainable and minimizing the duplicative reporting period as much as practicable.

Two commenters requested that FINRA provide transparency and sufficient notice once the date for the retirement of OATS has been set.[78] As an initial matter, the process for retiring OATS is outlined in the Proposal. And, the Commission believes that FINRA is incented to make the requisite filing as far in advance as practicable in order to provide firms with sufficient notice and opportunity to prepare for the retirement of OATS to promote an orderly retirement of OATS. In addition, FINRA will provide as much transparency into the process as possible regarding issues relating to OATS retirement in its communications with firms.[79] The Plan Processor is required to provide a variety of error rate data to CAT Reporters and the Operating Committee under the CAT NMS Plan including daily statistics on rejection rates after the data has been processed.[80] During the 180-day assessment period, the Commission believes that it is appropriate for the SROs and the Plan Processor to provide this error rate data, as it will help Industry Members identify any problem areas and improve the accuracy of their CAT reporting. FINRA CAT currently provides regular updates to Industry Members regarding CAT implementation and compliance during FINRA CAT's Weekly Industry Testing Checkpoint and Monthly Implementation calls.[81] Also, the statistics provided by FINRA CAT will serve as a good proxy for progress toward achieving the requisite error rates for the purposes of OATS retirement.[82] Further, once FINRA has determined that such standards have been met, it has committed to file a rule filing for immediate effectiveness setting forth the basis for its determination and to publish a Regulatory Notice announcing the implementation date of SR–FINRA–2020–024.

V. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and

[72] *See* CAT NMS Plan, Section 6.5(d)(i); Appendix C, Section A.3(b); Appendix C, Section A.3(b), n. 102.

[73] *See* CAT NMS Plan, Section 1.1. *See also* 17 CFR 242.613(j)(6). ''The term *error rate* shall mean the percentage of reportable events collected by the central repository in which the data reported does not fully and accurately reflect the order event that occurred in the market.'' *Id.*

[74] *See* CAT NMS Plan, Appendix C, Section A.2(a); Appendix D, Section 6.

[75] *See* FIF Letter, *supra* note 5.

[76] CAT NMS Plan, Appendix C, Section C.9.

[77] FINRA hosts a number of industry outreach events. For the list of upcoming FINRA events, *see https://www.finra.org/events-training.* Separately, FINRA CAT also hosts a number of industry update calls and events. For a list of upcoming industry outreach events, *see https://catnmsplan.com/events.*

[78] *See* FIF Letter and Refinitiv Letter, *supra* note 5.

[79] *See* Response Letter, *supra* note 6.

[80] *See* CAT NMS Plan, Section 6.1(o)(v); CAT NMS Plan, Appendix C, Section A.3(b); CAT NMS Plan, Appendix D, Section 10.4.

[81] *See* Response Letter, *supra* note 6.

[82] *Id.*

arguments concerning the foregoing, including whether Amendment No. 1 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–FINRA–2020–024 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–2020–024. 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 and on its internet website. 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–2020–024 and should be submitted on or before December 28, 2020.

VI. Accelerated Approval of Proposed Rule Change As Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the 30th day after the date of publication of notice of the filing of Amendment No. 1 in the **Federal Register**. As discussed above, the proposed rule change, as modified by Amendment No. 1, would eliminate the OATS Rules as duplicative systems of the CAT, after Industry Members and able to demonstrate reliable and accurate reporting to the CAT with a reasonable rate of errors, and after FINRA is able to ascertain that (1) usage of CAT Data over the assessment period has not revealed material issues that have not been corrected; (2) the CAT includes all data necessary to allow FINRA to continue to meet its surveillance obligations; and (3) the Plan Processor is sufficiently meeting all of its obligations under the CAT NMS Plan. The Commission believes that the proposal is consistent with these provisions of the CAT NMS Plan and consistent with the Act because they are reasonably designed to assist the SROs in meeting their regulatory obligations pursuant to Rule 613 and the Plan.

In Amendment No. 1, FINRA modified the method by which the equity exchange match rate would be calculated. Specifically, FINRA proposed that instead of calculating the equity exchange match rate on a per exchange basis, it would calculate the match rate in the aggregate across all exchanges. The Commission believes that such a calculation is consistent with the current reporting published by FINRA CAT and as such will be easier for industry members to understand. The Commission believes Amendment No. 1 does not materially modify the substance of the proposed rule change as it was initially filed, but merely provides for a more straightforward method for calculating the equity exchange match rates.

Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act, to approve the proposed rule change, SR–FINRA–2020–024, as modified by Amendment No. 1, on an accelerated basis.[83]

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (SR–FINRA–2020–024), as modified by Amendment No. 1, be and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[84]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26677 Filed 12–3–20; 8:45 am]

BILLING CODE 8011–01–P

[83] 15 U.S.C. 78s(b)(2).

[84] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 16603 and # 16604; California Disaster Number CA–00325]

Presidential Declaration Amendment of a Major Disaster for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 9.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of California (FEMA—4558—DR), dated 08/22/2020.

Incident: Wildfires.

Incident Period: 08/14/2020 through 09/26/2020.

DATES: Issued on 11/21/2020.

Physical Loan Application Deadline Date: 12/11/2020.

Economic Injury (EIDL) Loan Application Deadline Date: 05/24/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT:

A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of California, dated 08/22/2020, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 12/11/2020.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2020–26663 Filed 12–3–20; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 16788 and # 16789; California Disaster Number CA–00331]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of California (FEMA–4569–DR), dated 11/25/2020.

Incident: Wildfires.

Incident Period: 09/04/2020 through 11/17/2020.

DATES: Issued on 11/25/2020.

Physical Loan Application Deadline Date: 01/25/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 08/25/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 11/25/2020, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Del Norte, Fresno, Madera, Mendocino, Napa, Shasta, Siskiyou, Sonoma.

The Interest Rates are:

For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere ...	2.750
Non-Profit Organizations Without Credit Available Elsewhere	2.750
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 167885 and for economic injury is 167890.

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2020–26665 Filed 12–3–20; 8:45 am]

BILLING CODE 8026–03–P

STATE JUSTICE INSTITUTE

Board of Directors Meeting, Notice

AGENCY: State Justice Institute.

ACTION: Notice of meeting.

SUMMARY: The SJI Board of Directors will be meeting on Monday, December 7, 2020 at 3:00 p.m. ET. The purpose of this meeting is to consider grant applications for the 1st quarter of FY 2021, and other business.

FOR FURTHER INFORMATION CONTACT: Jonathan Mattiello, Executive Director, State Justice Institute, 11951 Freedom Drive, Suite 1020, Reston, VA 20190, (571) 313–8843, *contact@sji.gov.*

Authority: Section 204(j) of the SJI Authorization Act (42 U.S.C. 10703 *et seq.*), 5 U.S.C. Section 552b.

Jonathan D. Mattiello,

Executive Director.

[FR Doc. 2020–26635 Filed 12–3–20; 8:45 am]

BILLING CODE P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36328]

Ken Tenn Regional Rail Partners, Inc.—Construction & Operation Exemption—In Fulton County, Ky. and Obion County, Tenn.

On September 2, 2020, Ken Tenn Regional Rail Partners, Inc. (KTRRP), a noncarrier, filed a petition for exemption under 49 U.S.C. 10502 from the prior approval requirements of 49 U.S.C. 10901 for authorization to construct and operate approximately 12.17 miles of rail line (Line) between milepost TennKen 51.69 at the Hickman-Fulton County River Port (Port) in Fulton County, Ky., and milepost UCT 450 near Union City, in Obion County, Tenn.

KTRRP asks that the Board issue a preliminary decision addressing the transportation merits of the construction project while the environmental review is ongoing. As discussed below, the Board concludes that such an approach is appropriate here and preliminarily concludes, subject to completion of the ongoing environmental review, that the proposed construction meets the statutory standards for exemption under section 10502. This decision only addresses the transportation merits, however, and does not grant the exemption or allow construction to begin. After the Board has considered the potential environmental impacts associated with this proposal, it will issue a final decision either granting the exemption, with conditions if appropriate, or denying it.

Background

KTRRP states that it is a non-profit corporation created to construct and operate the Line by the Fulton County Industrial Development Authority of Kentucky, which provides assistance with economic development in Fulton County, and the Industrial Development Board of the City of Union City, which is an economic development agency and sub-entity of Union City. (Pet. 3.) [1]

The petition states that the Port is a public entity that provides bulk and break-bulk cargo transfer operations for a variety of commodities and transloading transfer service, storage, and rail service. (*Id.* at 3–4.) Rail service at the Port is provided by the TennKen Railroad Company (TennKen), which connects with Canadian National Railway Company (CN) at Dyersburg, Tenn. (*Id.* at 4.)

As noted above, the proposed Line would begin at the Port at milepost TennKen 51.69, near the Mississippi River, and extend to milepost UCT 450 in Obion County. (*Id.* at 2.) According to KTRRP, two separate segments of the Line, totaling 3.47 miles, would be built over existing rights-of-way that are not currently in use: One would run from Union City to the north, on the west side of Tennessee Highway 21 to the Tennessee/Kentucky state line and then along the west side of Kentucky State Route 239 to Kentucky State Route 166; the other would parallel the east side of Kentucky Highway 125 just north of Kentucky Highway 166 for approximately 0.75 miles. The remainder of the Line would be newly constructed right-of-way running east to west until connecting to TennKen in Fulton County, Ky. (*Id.* at 6, Ex. B, Joint V.S. Billingsley & Curlin 3.) KTRRP notes that the proposed Line ultimately would join TennKen with the Union City Terminal Railroad to create a 46.1-mile loop connecting with CN at both Dyersburg and Rives, Tenn. (Pet., Ex. B, Joint V.S. Billingsley & Curlin 4.)

KTRRP states that the proposed Line is located in an area that is a ''lightly

[1] KTRRP states that it intends to contract with a Class III rail carrier to operate over the proposed Line. (Pet. 5.)

settled, economically depressed, agricultural region.'' (Pet. 6.) KTRRP asserts that the proposed Line would support economic development by providing the Port and local industrial facilities with easier and more cost-effective access to the interstate rail network. Specifically, a connection through Union City would allow the Port to utilize grain elevators in Union City and to transport outbound dried distillers' grain from local ethanol production. (*Id.* at 7, Ex. B, Joint V.S. Billingsley & Curlin 4.) KTRRP states that the current transportation option for most shippers to the east of the Port is via truck along Tennessee Highway 5/ Kentucky State Highway 125. (Pet. 7)

KTRRP argues that regulation of the construction and operation of the proposed Line is not needed to carry out the rail transportation policy (RTP) at 49 U.S.C. 10101, and the transaction is of limited scope. (*Id.* at 9–10.) Alternatively, it argues that application of section 10101 is not necessary to protect shippers from an abuse of market power. (*Id.* at 11.) KTRRP argues that an exemption is consistent with sections 10101(2) and 10101(7), as it would minimize the need for federal regulatory control over the rail transportation system and reduce regulatory barriers to entry. (*Id.* at 10.) Additionally, KTRRP asserts that the exemption would satisfy sections 10101(4) and 10101(5), because it would provide an alternative means of transportation and/or enhance competition and the proposed Line meets a public need. (*Id.*)

KTRRP asserts that a preliminary determination on the transportation merits is appropriate here because its proposed construction is a transportation and economic development project that has already received funding and other support from the state governments of Kentucky and Tennessee, as well as local governments in the region. (*Id.* at 12.) It further explains that a preliminary approval on the transportation merits will support fundraising and planning efforts, demonstrate that additional investment of state and local resources is warranted, and remove any uncertainty concerning the transportation benefits of the proposed Line. (*Id.*)

On October 8, 2020, U.S. Representative James Comer filed a letter in support of KTRRP's petition. No party has filed in opposition to the petition.

Discussion and Conclusions

The construction of new railroad lines that are to be part of the interstate rail network requires prior Board authorization, either through issuance of a certificate under 49 U.S.C. 10901 or, as requested here, through an exemption under 49 U.S.C. 10502 from the formal application procedures of section 10901. Section 10901(c) directs the Board to grant rail construction proposals unless it finds the proposal ''inconsistent with the public convenience and necessity.'' *See Alaska R.R.—Constr. & Operation Exemption—A Rail Line Extension to Port MacKenzie, Alaska,* FD 35095, slip op. at 5 (STB served Nov. 21, 2011), *aff'd sub nom. Alaska Survival* v. *STB,* 705 F.3d 1073 (9th Cir. 2013) (addressing the Board's construction exemption process).

Under 49 U.S.C. 10502(a), however, ''the Board, to the maximum extent consistent with [Part A], shall exempt'' a transaction (including a construction proposal) from the prior approval requirements of section 10901 when it finds that: (1) Regulation is not necessary to carry out the RTP of 49 U.S.C. 10101; and (2) either (a) the transaction is of limited scope or (b) application of the statutory provision is not needed to protect shippers from the abuse of market power.

Issuance of Preliminary Decision on the Transportation Merits

As noted above, KTRRP requests that the Board issue a preliminary decision addressing the transportation merits of the project in advance of a decision on the environmental issues. KTRRP asserts that a preliminary decision addressing the transportation issues would support continued fundraising and planning, demonstrate that additional investment of state and local resources is warranted, and remove any uncertainty concerning the transportation benefits of the proposed Line. (Pet. 11–12.)

The Board has considered requests for preliminary decisions addressing the transportation merits of a project over the years.[2] Here, KTRRP has received support for the project from state and local entities and is seeking further investment assistance; the transportation merits of the project, which would support regional economic development, are apparent, as discussed in this decision; and there is no opposition to either the request for preliminary decision or the exemption itself. In these circumstances, the Board finds it appropriate to issue a preliminary decision while the Board continues the environmental review of the proposed construction.

Rail Transportation Analysis

Based on the record, the Board preliminarily concludes that the proposed construction, which is unopposed on the transportation merits, qualifies for an exemption under section 10502 from the formal application procedures of section 10901. First, regulation under section 10901 is not necessary to carry out the RTP. The record here shows that the proposed Line would provide enhanced rail service to and from the Port and surrounding area. Currently, the primary transportation option for shippers east of the Port is via trucks. The connection through Union City would provide local industrial facilities access to the interstate rail network and allow traffic to utilize grain elevators and to transport outbound dried distillers' grain. The proposed Line would enhance competition by providing shippers in the area with an additional and more cost-effective freight option and foster sound economic conditions, consistent with 49 U.S.C. 10101(4) and (5). Exempting the proposed construction from the requirements of section 10901 would also minimize unnecessary expense associated with the preparation and filing of a formal construction application, expedite regulatory decisions, and reduce regulatory barriers to entry for the Line in furtherance of 49 U.S.C. 10101(2), (7) & (15). Other aspects of the RTP would not be adversely affected.

In addition, application of section 10901 is not necessary to protect shippers from an abuse of market power.[3] Because shippers would be gaining additional and improved transportation options (with no reduction in service options), the proposed Line would enhance competition.

Environmental Review

As discussed above, the Board has preliminarily concluded that the proposed construction meets the statutory standards for exemption, subject to completion of the ongoing environmental review. KTRRP has consulted with the Board's Office of

[2] *See Six Cnty. Ass'n of Gov'ts—Constr. & Operation Exemption—A Rail Line Between Levan & Salina, Utah,* FD 34075 (STB served Sept. 3, 2015); *Alaska R.R.—Constr. & Op. Exemption—Rail Line Between Eielson Air Force Base and Fort Greely, Alaska,* FD 34658 (STB served Oct. 4, 2007); *Burlington N. & Santa Fe Ry.—Constr. & Op. Exemption—Merced Cnty., Cal.,* FD 34305 (STB served Mar. 28, 2003).

[3] Because regulation of the proposed construction and operation is not needed to protect shippers from the abuse of market power, the Board need not determine whether the transaction is limited in scope. 49 U.S.C. 10502(a)(2).

Environmental Analysis (OEA) regarding the environmental review process. By letter dated May 29, 2020, KTRRP requested a waiver of the requirements of 49 CFR 1105.6(a), which generally requires the preparation of an Environmental Impact Statement for rail construction and operation proposals. OEA granted the request on June 9, 2020, finding that preparation of an Environmental Assessment (EA) is the appropriate level of environmental documentation for this proceeding. OEA currently is preparing a Draft EA and any associated historic or cultural review that will be made available for public comment. Following the conclusion of the environmental review process, the Board will issue a further decision assessing the potential environmental impacts of the construction proposal and determining whether the exemption will become finally effective (subject to appropriate mitigation conditions, if necessary). *See Mo. Mining, Inc.* v. *ICC,* 33 F.3d 980 (8th Cir. 1994).

The decision issued today does not prejudge the Board's final decision, nor diminish the agency's environmental review process concerning the proposed Line's construction. *See Ill. Com. Comm'n* v. *ICC,* 848 F.2d 1246, 1259 (DC Cir. 1988). Construction may not begin until the Board's final decision in this proceeding has been issued and has become effective.

It is ordered:

1. Under 49 U.S.C. 10502(b), a proceeding is instituted.

2. Under 49 U.S.C. 10502, the Board preliminarily exempts the construction of the above-described Line from the prior approval requirements of 49 U.S.C. 10901, subject to further consideration of the potential environmental impacts of the proposal.

3. On completion of the environmental review, the Board will issue a further, final decision addressing any potential environmental impacts and determining whether the exemption should become effective (subject to any appropriate mitigation conditions). Construction may not begin until the Board's final decision has been issued and has become effective.

4. Notice of this decision will be published in the **Federal Register**.

5. Petitions to reconsider must be filed by December 21, 2020.

6. This decision is effective 30 days from the date of service.

Decided: November 30, 2020.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2020–26659 Filed 12–3–20; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Random Drug and Alcohol Testing Percentage Rates of Covered Aviation Employees for the Period of January 1, 2021, Through December 31, 2021

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA has determined that the minimum random drug and alcohol testing percentage rates for the period January 1, 2021, through December 31, 2021, will remain at 25 percent of safety-sensitive employees for random drug testing and 10 percent of safety-sensitive employees for random alcohol testing.

FOR FURTHER INFORMATION CONTACT: Ms. Vicky Dunne, Office of Aerospace Medicine, Drug Abatement Division, Program Policy Branch (AAM–820), Federal Aviation Administration, 800 Independence Avenue SW, Room 806, Washington, DC 20591; Telephone (202) 267–8442.

Discussion: Pursuant to 14 CFR 120.109(b), the FAA Administrator's decision on whether to change the minimum annual random drug testing rate is based on the reported random drug test positive rate for the entire aviation industry. If the reported random drug test positive rate is less than 1.00%, the Administrator may continue the minimum random drug testing rate at 25%. In 2019, the random drug test positive rate was 0.731%. Therefore, the minimum random drug testing rate will remain at 25% for calendar year 2021.

Similarly, 14 CFR 120.217(c), requires the decision on the minimum annual random alcohol testing rate to be based on the random alcohol test violation rate. If the violation rate remains less than 0.50%, the Administrator may continue the minimum random alcohol testing rate at 10%. In 2019, the random alcohol test violation rate was 0.114%. Therefore, the minimum random alcohol testing rate will remain at 10% for calendar year 2021.

SUPPLEMENTARY INFORMATION: If you have questions about how the annual random testing percentage rates are determined please refer to the Code of Federal Regulations Title 14, section 120.109(b) (for drug testing), and 120.217(c) (for alcohol testing).

Issued in Washington, DC.

Brett A. Wyrick,

Acting Federal Air Surgeon.

[FR Doc. 2020–26749 Filed 12–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2019–0165]

Nationwide Freight Systems, et al.; Petition for Determination of Preemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of petition for determination of preemption; request for comments.

SUMMARY: FMCSA requests comments on a petition submitted by Nationwide Freight Systems, Inc., Leader U.S. Messenger, Inc., and Stott Contracting, LLC, requesting a determination that certain carrier identification requirements imposed by the Illinois Commerce Commission are preempted by 49 U.S.C. 14506.

DATES: Comments must be received on or before January 4, 2021.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Number FMCSA–2019–0165 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* See the *Public Participation and Request for Comments* section below for further information.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the *Privacy Act* heading below.

FOR FURTHER INFORMATION CONTACT: Frederic L. Wood, Legislative and Regulatory Affairs Division; FMCSA

Office of Chief Counsel; Telephone: (202) 493–0349; Email: *Frederic.Wood@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2019–0165), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number, ''FMCSA–2019–0165'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

Comments received after the closing date will be considered to the extent practicable. FMCSA may, however, issue a final determination at any time after the close of the comment period. 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 monitor the public docket for new material.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the DOT Headquarters West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year.

Privacy Act: DOT solicits comments from the public to better inform its preemption determinations. 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.transportation.gov/privacy.*

Background

On May 26, 2017, Nationwide Freight Systems, Inc., Leader U.S. Messenger, Inc., and Stott Contracting, LLC (''petitioners'') submitted a petition to FMCSA requesting a determination that certain identification requirements imposed on motor carriers by the Illinois Commerce Commission are preempted by Federal law. Petitioners are motor carriers operating both in interstate commerce and in intrastate commerce within Illinois.

The provisions of an Illinois statute are involved in this matter. Specifically, 625 ILCS 5/18c-4104, entitled ''Unlawful Operations,'' states, in part:

(1) Prohibition. Except as provided in Article I of this Sub-chapter [625 ILCS 5/18c-4101 *et seq.*], and subject to the provisions stated herein, it shall be unlawful for any person to:

(a) Operate as an intrastate motor carrier of property without a license from the Commission; or as an interstate motor carrier of property without a registration from the Commission.

* * * * *

(c) Operate, as an intrastate motor carrier of property, any motor vehicle which does not carry a copy of a valid, current license issued by the Commission to such carrier; or operate, as an interstate motor carrier of property, any motor vehicle which does not carry a copy of a valid, current registration issued by the Commission to such carrier; or fail to produce such copy on request; provided that an authorized interstate motor carrier of property shall be exempted from the requirement that a copy of its registration be carried in each motor vehicle.

* * * * *

(f) Operate, as an intrastate motor carrier of property, any motor vehicle for which the carrier has not executed a prescribed intrastate cab card, with current Illinois intrastate identifier printed thereon; or, as an interstate motor carrier of property, any motor vehicle for which the carrier has not executed a prescribed interstate cab card, with current Illinois interstate identifier affixed or printed thereon.

(g) Operate, as an intrastate motor carrier of property, any motor vehicle which does not carry the properly executed intrastate cab card, with current Illinois intrastate identifier printed thereon; or, as an interstate motor carrier of property, any motor vehicle which does not carry the properly executed interstate cab card, with current Illinois interstate identifier affixed or printed thereon.

* * * * *

The proviso at the end of subsection (c) above exempts interstate motor carriers of property from the requirement to carry a copy of their registration in each vehicle such carriers operate. But there is no exemption provided in the statute for such carriers from the requirement to execute and carry a cab card in each vehicle, as provided in subsections (f) and (g).

Illinois Commerce Commission regulations also include requirements for executing and carrying cab cards in motor vehicles operated by motor carriers:

(a) Cab cards/identifiers shall be executed, carried, or presented in satisfaction of the requirements of the Illinois Commercial Transportation Law . . ., [92 Ill. Administrative Code] Part [1302], or Commission orders no earlier than December 1 preceding the calendar year for which fees were paid, and no later than February 1 of the calendar year for which fees were paid . . ..

(b) A vehicle operated in both intrastate and interstate commerce must carry both an intrastate and an interstate cab card/identifier.

92 Ill Administrative Code 1302.15.

Applicable Law

Petitioners have requested a determination that both the licensing and registration (public carrier certificate) and cab card requirements of the statute and the Illinois Commerce Commission regulations are preempted under 49 U.S.C. 14506. This statute provides that no State, political subdivision of a State, interstate agency, or other political agency of two or more States may enact or enforce any law, rule, regulation standard, or other provision having the force and effect of law that requires a motor carrier, motor private carrier, freight forwarder, or leasing company to display any form of identification on or in a commercial motor vehicle (''CMV,'' as defined in 49 U.S.C. 14504a(a)(1)), other than forms of identification required by the Secretary of Transportation under 49 CFR 390.21.[1]

[1] 49 U.S.C. 14506(a) enacted by section 4306(a) of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), Pub. Law 109–59, 119 Stat. 1773 (Aug. 10, 2005).

The applicable definition of CMV for section 14506 is in section 14504a(a)(1) (which incorporates the CMV definition in 49 U.S.C. 31101), and states that a CMV is a self-propelled or towed vehicle used on the highways in commerce principally to transport passengers or cargo, if the vehicle: (1) Has a gross vehicle weight rating or gross vehicle weight of at least 10,001 pounds, whichever is greater; (2) is designed to transport more than 10 passengers including the driver; or (3) is used in transporting material determined to be hazardous under 49 U.S.C. 5103 and in a quantity requiring placarding as provided in regulations prescribed under 49 U.S.C. 5103.

There are two important aspects of this definition that are relevant to any determination under section 14506: (1) It applies to a CMV used ''in commerce,'' which means that it applies to vehicles operated either in intrastate or in interstate transportation; (2) the definition is slightly different from the definition of CMVs used to transport property subject to safety regulation under 49 U.S.C. 31131–51. See 49 U.S.C. 31132(1). Note also that provisions relating to CMVs used to transport passengers are not relevant to the preemption determination under consideration here, as the Illinois statutes and regulations in question apply only to vehicles transporting property (including hazardous materials).

Section 14506 also includes several exceptions to its general prohibitions. A State may continue to require display of credentials that are required: (1) Under the International Registration Plan under 49 U.S.C. 31704; (2) under the International Fuel Tax Agreement under 49 U.S.C. 31705, or under an applicable State law if, on October 1, 2006, the State had a form of highway use taxation not subject to collection through the International Fuel Tax Agreement; (3) under a State law regarding motor vehicle license plates or other displays that the Secretary determines are appropriate; (4) in connection with Federal requirements for hazardous materials transportation under 49 U.S.C. 5103; or (5) in connection with the Federal vehicle inspection standards under 49 U.S.C. 31136. 49 U.S.C. 14506(b).

Request for Comments

FMCSA seeks comments in response to this petition. Comments are specifically requested on whether the registration and cab card requirements involved (625 ILCS 5/18c-4104(c), (f) and (g)) should be determined to be ''appropriate'' under the discretionary authority in 49 U.S.C. 14506(b)(3) providing that a State may require display of credentials under a State law requiring motor vehicle license plates or other displays the Secretary deems appropriate. Commenters are also encouraged to submit information on the effects of the requirements on safety, operations, and the economics of motor carriers operating in the State of Illinois.

FMCSA requests commenters to limit their submissions to these issues and to submit data supporting their positions. The Agency has placed the petition in the docket (No. FMCSA–2019–0165).

James W. Deck,

Deputy Administrator.

[FR Doc. 2020–26668 Filed 12–3–20; 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 final disposition; grant of exemption.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its decision to grant K & L Trucking, Inc.'s (K & L) application for a limited 5-year exemption to allow the company to secure large metal coils to its trailers using a cargo securement system that differs from that required by the Federal Motor Carrier Safety Regulations (FMCSRs). The Agency has determined that granting the exemption would likely achieve a level of safety equivalent to or greater than the level of safety provided by the regulation.

DATES: This exemption is effective December 4, 2020 and expires on December 4, 2025.

FOR FURTHER INFORMATION CONTACT: Mr. Luke Loy, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, (202) 366–0676, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Docket: For access to the docket to read background documents or comments submitted to notice requesting public comments on the exemption application, go to *www.regulations.gov* at any time or visit Dockets Operations, Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, 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. The on-line Federal document management system is available 24 hours each day, 365 days each year. The docket number is listed at the beginning of this notice.

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the FMCSRs. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public 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 safety analyses and public comments submitted, 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)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

K & L's Application for Exemption

K & L applied for an exemption from 49 CFR 393.120(c) to allow the carrier to secure large metal coils to its trailers using a cargo securement system that differs from that required by the FMCSRs. A copy of the application is included in the docket referenced at the beginning of this notice.

K & L Trucking is a corporation located at 490 West Main Street, Delta, Ohio 43515. K & L's business consists entirely of transporting metal coils from North Star Blue Scope Steel, LLC, located at 6767 County Road 9, Delta, Ohio 43515, to Fulton County Processing, located at 7800 Ohio-109, Delta, Ohio 43515. The two businesses are less than 2 miles apart, and K & L's trucks never travel faster than 30 miles

per hour on the road, as the drive is simply too short for the trucks to accelerate to a higher speed.

Section 393.120(c) of the FMCSRs requires that 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 seeks an exemption to use an alternative securement system consisting of a customized metal carrier affixed to the bed of its trailers and the use of a single large cargo securement strap. The coil carriers weigh 2,500 pounds each and are attached to the bed with sixteen ⅝ inch, Grade 8 bolts with a working load limit of 27,611 pounds each. In total, the carrier and bolts have a working load limit over 500,000 pounds. Rather than using four chains to prevent the coil from moving forward or backwards, K & L uses a large single, two-ply, nylon-Kevlar tiedown strap with a working load limit of 44,800 pounds through the eye of the coil and secures the coil to the metal carrier.

K & L states that the alternative cargo securement system will not have an adverse impact on safety, and that adherence to the terms and conditions of the exemption would likely achieve a level of safety equivalent to or greater than the level of safety achieved without the exemption.

Comments

FMCSA published a notice of the application in the **Federal Register** on May 14, 2020 and asked for public comment (85 FR 29018). The Agency received one comment, from Mr. Bruce Grimm. Mr. Grimm stated that the proposed cargo securement technique proposed by K & L may be practical if the strength of the load securement is consistently monitored by the motor carrier, and stated that the heavy-duty load securement straps proposed to be used by K & L have been successfully used in other transportation cargo securement applications. Mr. Grimm wrote that these cargo securement straps are not immune to damage and may be subject to deterioration due to ultraviolet light.

FMCSA Decision

The FMCSA has evaluated the K & L exemption application, and the comment received. The Agency believes that granting the temporary exemption to allow K & L Trucking to transport metal coils using an alternative securement system consisting of a customized metal carrier affixed to the bed of its trailers and the use of a single large cargo securement strap will likely provide a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

FMCSA acknowledges the concerns of commenter Mr. Bruce Grimm that the synthetic cargo securement strap and metal coil carrier proposed to be used by K & L must be inspected frequently to identify any damage that might affect the working load limit of the metal coil carrier or the single large synthetic cargo strap. FMCSA believes that the current FMCSRs at section 393.104(b) which requires that ''all tiedowns and cargo securement systems, parts and components used to secure cargo must be in proper working order when used to perform that function with no damaged or weakened components, such as, but not limited to, cracks or cuts that will adversely affect their performance for cargo securement purposes, including reducing the working load limit,'' ensures that the carrier will be effective in monitoring the condition of the cargo securement system. FMCSA believes that the alternative cargo securement technique of metal coil carrier and the single large synthetic cargo strap is likely to provide a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

Terms and Conditions for the Exemption

The Agency hereby grants the exemption for a 5-year period, beginning December 4, 2020 and ending December 4, 2025. During the temporary exemption period, K & L will be allowed to use an alternative securement system consisting of a customized metal carrier affixed to the bed of its trailers and the use of a single large cargo securement strap. The coil carriers weigh 2,500 pounds each and are attached to the bed with sixteen ⅝ inch, Grade 8 bolts with a working load limit of 27,611 pounds each, and a large single, two-ply, nylon-Kevlar tiedown strap with a working load limit of 44,800 pounds through the eye of the coil to secures the coil to the metal carrier for the limited transport from North Star Blue Scope Steel, LLC, located at 6767 County Road 9, Delta, Ohio 43515, to Fulton County Processing, located at 7800 Ohio-109, Delta, Ohio 43515.

The exemption will be valid for 5 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) K & L 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 before it was 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).

Interested parties possessing information that would demonstrate that the cargo securement system used by K & L to secure metal coils is not achieving the requisite statutory level of safety should immediately notify FMCSA. The Agency will evaluate any such information and, if safety is being compromised or if the continuation of the exemption is not consistent with 49 U.S.C. 31136(e) and 31315(b), will take immediate steps to revoke the exemption.

Preemption

In accordance with 49 U.S.C. 31313(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

James W. Deck,

Deputy Administrator.

[FR Doc. 2020–26669 Filed 12–3–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request on Burden Related to Requirement To Use Taxpayer Identifying Numbers on Submissions Under the Section 897 and 1445

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to

comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the burden related to the guidance under sections 897, 1445, and 6109 to require use of Taxpayer Identifying Numbers on submission under the section 897 and 1445.

DATES: Written comments should be received on or before February 2, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Guidance under Sections 897, 1445, and 6109 to require use of Taxpayer Identifying Numbers on Submission under the Section 897 and 1445.

OMB Number: 1545–1797.

Regulation Project Number: TD 9082; TD 9751.

Abstract: The collection of information relates to applications for withholding certificates under section 1.1445–3 to be filed with the IRS with respect to (1) dispositions of U.S. real property interests that have been used by foreign persons as a principle residence within the prior 5 years and excluded from gross income under section 121 and (2) dispositions of U.S. real property interests by foreign persons in deferred like kind exchanges that qualify for nonrecognition under section 1031.

Current Actions: There is no change to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households and Business or other for-profit.

Estimated Number of Responses: 150.

Estimated Time per Respondent: 4 hrs.

Estimated Total Annual Burden Hours: 600.

The following paragraph applies to all the collections of information covered by this notice:

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.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- 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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 30, 2020.

Ronald J. Durbala,

IRS Tax Analyst.

[FR Doc. 2020–26657 Filed 12–3–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request on Burden Related to Information Reporting by Passport Applicants

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the burden related to the information reporting by passport applicants.

DATES: Written comments should be received on or before February 2, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Information Reporting by Passport Applicants.

OMB Number: 1545–1359.

Regulation Project Number: TD 9679.

Abstract: These final regulations provide information reporting rules for certain passport applicants. These final regulations apply to certain individuals applying for passports (including renewals) and provide guidance to such individuals about the information that must be included with their passport application.

Current Actions: There is no change to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Responses: 12,133,537.

Estimated Time per Respondent: 6 min.

Estimated Total Annual Burden Hours: 1,213,354.

The following paragraph applies to all the collections of information covered by this notice:

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.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- 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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 30, 2020.

Ronald J. Durbala,

IRS Tax Analyst.

[FR Doc. 2020–26703 Filed 12–3–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 843

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), 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 information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 843, Claim for Refund and Request for Abatement.

DATES: Written comments should be received on or before February 2, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke, at (202) 317–6009, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Claim for Refund and Request for Abatement.

OMB Number: 1545–0024.

Form Number: 843.

Abstract: Internal Revenue Code section 6402, 6404, and sections 301.6402–2, 301.6404–1, and 301.6404–3 of the regulations allow for refunds of taxes (except income taxes) or refund, abatement, or credit of interest, penalties, and additions to tax in the event of errors or certain actions by the IRS. Form 843 is used by taxpayers to claim these refunds, credits, or abatements.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, not-for-profit institutions, farms, and state, local or tribal governments.

Estimated Number of Responses: 550,500.

Estimated Time per Respondent: 1 hr., 35 min.

Estimated Total Annual Burden Hours: 875,295.

The following paragraph applies to all the collections of information covered by this notice:

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. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

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.

Approved: November 18, 2020.

Chakinna B. Clemons,

Supervisory Tax Analyst.

[FR Doc. 2020–26757 Filed 12–3–20; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 85 Friday,

No. 234 December 4, 2020

Part II

Environmental Protection Agency

40 CFR Parts 60, 63, 79, et al.
Fuels Regulatory Streamlining; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60, 63, 79, 80, 1042, 1043, 1065 and 1090

[EPA–HQ–OAR–2018–0227; FRL–10014–97–OAR]

RIN 2060–AT31

Fuels Regulatory Streamlining

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action updates many of EPA's existing gasoline, diesel, and other fuel quality programs to improve overall compliance assurance and maintain environmental performance, while reducing compliance costs for industry and EPA. EPA is streamlining 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 applies to all gasoline, diesel, and other fuel quality programs. This action does not change the stringency of the existing fuel quality standards.

DATES: This rule is effective on January 1, 2021, except for amendatory instructions 48, 51, and 52, which are effective on December 4, 2020, and amendatory instructions 16, 18, and 19, which are effective on January 1, 2022. The incorporation by reference of certain publications listed in this regulation is approved by the Director of the Federal Register as of December 4, 2020. The incorporation by reference of ASTM D86–12, D93–13, D445–12, D613–13, D4052–11, and D5186–03 (R2009) in part 1065 was approved by the Director of the Federal Register as of June 27, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0227. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material is not available on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

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.*

SUPPLEMENTARY INFORMATION:

Does this action apply to me?

Entities potentially affected by this final 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 action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your entity would be affected by this action, you should carefully examine the applicability criteria in 40 CFR part 1090. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Table of Contents

I. Executive Summary

A. Overview of Fuels Regulatory Streamlining

1. Why EPA Is Taking This Action

In this action, we are streamlining and modernizing our 40 CFR part 80 (''part 80'') fuel quality regulations to minimize the implementation burden associated with them while still ensuring that the fuel quality standards previously established under the Clean Air Act (CAA) continue to be met in real-world use. We are doing so by transferring the relevant part 80 provisions into a new set of regulations in 40 CFR part 1090 (''part 1090''). After taking a detailed look at the many different and overlapping requirements in the part 80 regulations, it became apparent that a holistic update to the regulations was better accomplished by redrafting them into an entirely new part. The new part 1090 regulations will also better reflect how fuels, fuel additives, and regulated blendstocks are produced, distributed, and sold in today's marketplace and help regulated parties more easily identify regulatory requirements.

2. What Is and Is Not Covered in This Action

This action focuses primarily on streamlining and consolidating the gasoline and diesel fuel programs that reside in part 80.[1] To accomplish this, we are removing expired provisions and consolidating the remaining provisions from multiple fuel quality programs into a single set of provisions. 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 streamlining action combines these separate, now fully-implemented programs, all of which affect the same regulated parties, into a single, national fuel quality program.

The majority of this action's changes 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 impose any new standards on fuels. As such, this action is mostly a compilation of numerous, relatively minor changes to the existing provisions under part 80. Many of these 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 changes will lead to a more effective, efficient EPA fuel quality program.

While this action changes many aspects of our fuel quality programs, there are several areas of the part 80 regulations that remain unchanged even as those regulations are transposed into part 1090. Most importantly, this action does not change the stringency of the existing fuel quality standards. We are simply streamlining and consolidating the part 80 fuel quality programs into a single streamlined fuel quality program that will make compliance with the existing fuel quality standards established under part 80 more straightforward to implement and comply with. As a result, in addition to reducing costs, it may also enable improved fuel quality through increased compliance with our fuel quality standards. This action transfers the part 80 fuel quality standards mostly unchanged to part 1090, though in some cases we are modifying the form of a standard to translate it into a format more conducive to streamlining the regulations and ensuring in-use compliance.

With minor exceptions, this action also does not change the provisions of the RFS program, which will remain in subpart M of part 80, The subpart M regulations are mostly unique to the RFS program. However, since the RFS program uses similar, if not the same, reporting systems and compliance mechanisms for parties to demonstrate compliance, we are finalizing some parallel changes to help ensure that this consistency is maintained or enhanced as a result of this action. This will help ensure consistency in how parties comply with our regulatory requirements and report information to EPA. We received a number of comments asking for more substantive changes to the RFS program; we consider these comments outside the scope of this rulemaking.[2]

Finally, this action does not remove any statutory requirement for fuels specified by the CAA. For example, this action does not 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 remove cetane index limits for diesel fuel under

[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 Renewable Fuel Standard (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, which are established under CAA section 211(a), (b), (e) and (o), are significantly different in scope, and would involve different considerations to update those regulatory requirements.

[2] We also noted in the NPRM that we would treat these comments outside the scope of this action. See 85 FR 29036 (May 14, 2020). Additionally, we are not reopening any aspects of the RFS program or any RFS regulations, other than to make minor edits that are intended to ensure consistency with the new language used in part 1090.

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, we are not eliminating any requirement under the CAA for fuels and parties that make, distribute, and sell such fuels.

We recognize that while we are not changing the standards, in some cases, the consolidation of certain provisions may slightly, indirectly affect in-use fuel quality. For example, 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 national annual average sulfur level. On the other hand, the provisions that 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 streamlined fuels program will maintain the same overall level of fuel quality as the part 80 regulations. We discuss the cumulative costs and benefits of these changes in more detail in Section XIV.

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 taken action on three key elements that are included in part 1090:

- A simplification of the RFG summer volatile organic compound (VOC) standards.[3]
- 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 simplifying the RFG standards by translating the part 80 summer RFG VOC standard into an RVP per-gallon cap of 7.4 psi. This change allows us to remove the use of the Complex Model[4] as a requirement to certify batches of gasoline and remove all the provisions associated with demonstrating compliance on average. This change also allows for us to minimize the restrictions on the commingling of RFG and CG, allowing for a more fungible and efficient gasoline distribution system.

Under part 80, the main remaining difference between RFG and CG is the summer volatility. Under part 80, RFG's volatility is functionally controlled through a summer VOC performance standard determined with the Complex Model pursuant to CAA section 211(k). In contrast, CG volatility is controlled through the RVP per-gallon maximum standards established under CAA section 211(h). EPA has previously aligned the treatment of RFG and CG for NO_X performance through the Tier 2 gasoline sulfur program and toxics performance through the national gasoline benzene program.[5] This action aligns treatment for RFG and CG by translating the existing RFG VOC performance standard into a maximum RVP per-gallon standard, as is the case for CG in the summer. In Section V.A.2, we describe how the 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 quality standards. With this translation of the RFG summer VOC performance standards into a summer RFG maximum RVP per-gallon standard, the required controls on RFG fuel properties will be identical to the control of CG fuel properties, even though the RVP standards themselves will remain different.

Second, since the standards for volatility, benzene, and sulfur will be treated similarly for both RFG and CG, this will allow for the streamlining and consolidation of the compliance and enforcement provisions of the various part 80 gasoline quality programs into a single fuel quality program in part 1090. This consolidation will improve consistency, remove duplication, and ultimately reduce compliance burden on both regulated parties and EPA. For example, 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. In part 1090, we are consolidating the various gasoline reporting requirements into a single, unified annual reporting requirement.

Third, the streamlined fuel quality program aims to improve oversight of our fuel quality programs while reducing its cost. We hope to accomplish this by updating and improving the third-party oversight programs we already use in part 80. In part 1090, we are consolidating the four existing in-use survey programs into a single national in-use fuel quality survey. This program will help ensure that all fuels nationwide continue to meet EPA fuel quality standards when dispensed into vehicles and engines, not just at the fuel manufacturing facility gate. We are also replacing the RFG independent lab testing requirement with a voluntary national sampling and testing oversight program (NSTOP). The NSTOP will 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 updating and modernizing the annual attest engagement program. These updated procedures will help ensure the quality and consistency of reported information. Taken together, we believe these provisions will help improve oversight of our streamlined fuel quality program.

B. Summary of Stakeholder Involvement and Rule Development

We 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 fuels regulatory streamlining program achieved its goals

[3] CAA section 211(h)(1) requires EPA to establish volatility requirements—that is, a restriction on Reid Vapor Pressure (RVP)—during the high ozone season. To implement these requirements, under part 80, EPA defined ''high ozone season'' as the period from June 1 to September 15. Also under part 80, the regulations specify that all parties (except for retailers) must make and distribute gasoline meeting the RVP standards from May 1 through September 15 and calls this period the ''regulatory control period.'' In general practice by industry and for purposes of this preamble, the high ozone season and regulatory control period are referred to as the ''summer'' or ''summer season'' and gasoline produced to be used during the regulatory control period and high ozone season is called ''summer gasoline.'' EPA's regulations do not impose any volatility requirements on any type of blend of gasoline outside of the summer season. In part 1090, we are maintaining the terms regulatory control period and high ozone season as they are implemented under part 80.

[4] 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.*

[5] See 72 FR 8428 (February 26, 2007).

and that the final regulations were ready for a smooth implementation. This included making available four discussion drafts of the proposed regulations on our Fuels Regulatory Streamlining website.[6] We also held a three-day public workshop on a variety of topics in Chicago on May 21–23, 2018.[7] 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. The streamlined fuel quality program in this action reflects the valuable input of all those who provided feedback to EPA both before and after the proposal.

C. Timing

As discussed in more detail in Section III.B, most of the part 1090 regulations will 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 will provide for a smooth transition to the new regulatory requirements. This is supported by commenters who have had to prepare for this transition. However, we also received a number of comments requesting that certain provisions begin implementation at a later date due to the short lead time available. As discussed in Section III.B, we are allowing certain provisions to begin implementation at a later date.

D. Costs and Benefits

We do not anticipate changes in air quality as a result of this action. This is largely due to the fact that we are not making changes to the existing fuel quality standards. As such, we do not expect that regulated parties will 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.

We believe that this action will 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 largely arise from the reduction of the administrative costs on both 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 $40.4 million per year ($2019). Other savings associated with improving the fungibility of fuel and providing greater flexibility could potentially be even more significant but we have been unable to quantify these savings. Section XIV discusses in more detail the potential costs and benefits of this action.

II. Changes to Other Parts of Title 40

We are transferring several provisions in part 80 that are currently in effect to part 1090. These provisions are all discussed in the subsequent sections of this preamble and are now presented in a manner that makes them easier to understand. Within part 80, we are also removing subparts D, E, F, G, H, I, J, K, L, N, and O and appendices A and B to part 80 in their entirety, along with most of subpart B. 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 superseded by subpart O (Tier 3 Sulfur), and subpart J (MSAT1) was supplanted by subpart L (MSAT2)). However, in order to help enable the transition from part 80 to part 1090 and since a number of 2020 compliance demonstration requirements have deadlines in 2021 (*e.g.,* reporting, attest engagements), these part 80 provisions will remain in the CFR until the end of 2021.

We are not transferring some provisions from part 80 to part 1090. First, we are retaining the current RFS provisions in subpart M. We are making 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 will make it consistent with part 1090 and much easier to find terms.

Third, 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.

Finally, we received a comment concerning how to adapt or apply the filler-neck requirements for current and future vehicle designs. The commenter suggested that it would be inappropriate for EPA to carry-forward these provisions without significant changes to address issues related to current and future vehicle designs and that such an effort should be taken in a future rulemaking that specifically addresses these issues. We agree with commenter's suggestion to address these issues in a later rulemaking as such modifications to the filler-neck requirements were not proposed and thus, are outside the scope of this rulemaking. As a result, we are not finalizing the movement of the filler-neck provisions of 40 CFR 80.24 to part 1090. Those provisions in part 80 will continue to apply.

In addition, several commenters identified cross-references to part 80 in other parts of Title 40 that need to be revised to instead reference part 1090. We have made the revisions identified by the commenters and have updated cross-references in 40 CFR parts 60, 63, and 1043. We similarly determined that there were references to part 80 in 40 CFR parts 1042 and 1065. Most of these updated cross-references simply correct citations. These changes are discussed in more detail in Section 2 of the RTC document.

III. Structure of Regulations and General Provisions

This section describes the general structure of part 1090 (*i.e.,* the modified structure of the regulations to make them more accessible to users and readers of the regulations). This section also describes implementation dates, how we will treat prior approvals made under part 80, and our approach to consolidating the existing definitions in part 80. Finally, this section discusses key provisions (*e.g.,* the definition of fuels) in more detail, as these provisions are fundamental to the streamlined fuel quality program.

A. Structure of the Regulations

We are finalizing a regulatory 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

[6] See *https://www.epa.gov/diesel-fuel-standards/fuels-regulatory-streamlining.* The four discussion drafts are available in the docket for this action.

[7] See 83 FR 20812 (May 8, 2018).

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 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).

Under part 1090, subpart A contains general requirements that apply throughout the rest of the part. 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 provisions are described elsewhere in this preamble; for example, rounding of data is discussed Section VIII.F and batch numbering is discussed in Section VIII.G.

We are also including a list of general regulatory requirements for parties in subpart B. This subpart lays out the general regulatory requirements for regulated parties. This will help 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. We received feedback from several stakeholders that such a roadmap would be helpful for them to find and follow the regulatory requirements in part 1090 and would be especially helpful to those new to the regulations.

We also placed the standards for different fuels in separate subparts so as to make it easier for parties to identify the specific standards that apply to each fuel, regulated blendstock, and additive. We placed the gasoline-related standards and the diesel-related (plus IMO marine fuel) standards separately in subparts C and D, respectively. We are leaving subpart E reserved, as we may need to use that subpart for future standards and this will enable us to maintain subsequent subparts to avoid unnecessary confusion within regulated community.

The next block of subparts (F through Q) 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 (*e.g.,* we have consolidated all the registration sections of part 80 into 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 manufacturer or oxygenate blenders).

Subpart R includes the liability, compliance, and violation provisions that EPA will use to enforce the program. This subpart consolidates the similar sections from across part 80 into a single streamlined subpart.

Finally, subpart S includes the attest engagement procedures that auditors will use to conduct annual auditing of reports and records for gasoline manufacturers. These procedures are updated versions of the those previously included in part 80.

We believe that this new structure will 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. In general, comments received on the structure were supportive of the ease and clarity with which regulatory requirements were laid out. Therefore, we are finalizing the regulatory structure in part 1090 as proposed.

B. Implementation Dates

We are finalizing the implementation date for most provisions of part 1090 on January 1, 2021. This implementation date will result in the first compliance reports under the new part 1090 regulations being due March 31, 2022, for the 2021 compliance period, and the first attest engagement reports being due June 1, 2022.

We believe that this schedule minimizes the need for immediate changes to how regulated parties comply with our fuel quality regulations, and therefore 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 will result from consolidating the programs into a single national program. Where possible, we wrote the requirements to allow flexibility for regulated parties to adjust as needed. We also believe that this schedule honors the significant effort and commitment that those impacted by the regulations have already put into their plans to transition from part 80 to part 1090 compliance.

In the NPRM, we sought comment on whether regulated parties needed more lead time to comply with any of the proposed regulatory provisions. While we received strong support for most provisions beginning on January 1, 2021, we received many comments suggesting that certain provisions of part 1090 be implemented at a later date to provide sufficient lead time but without impacting the overall implementation schedule. In particular, commenters highlighted the product transfer document (PTD) requirements and the NSTOP provisions as two areas where more lead time is needed.

For PTDs, several commenters suggested that it will take several months to modify computer systems to print the appropriate language on PTDs and work with pipelines and other distributors of fuels to develop the necessary product codes to comply with the part 1090 PTD requirements. They expressed concern that the time between when this action is finalized and its implementation on January 1, 2021, may not allow sufficient lead time, and suggested that we allow regulated parties to begin complying with the PTD provisions no later than May 1, 2021. This would then coincide with the next natural change in the marketplace with the onset of the summer RVP requirements in gasoline. Since the need for PTD changes is also less important prior to May 1, 2021, as RFG and CG are fungible in the winter under part 1090, we are delaying the

PTD implementation date until May 1, 2021, as requested. However, parties may opt to comply with the part 1090 PTD requirements earlier than May 1, 2021.

Regarding the NSTOP, parties noted that the mechanics of signing up with an independent surveyor, having EPA approve a plan, and then to begin having the independent surveyor obtain samples from fuel manufacturing facilities would require several months. Commenters also noted that since the program was new, there were several details that would need to be worked out in advance prior to the NSTOP being able to be implemented. Commenters also requested that if EPA did grant more lead time for the NSTOP, that the number of visits under the NSTOP should be adjusted to account for the fact that the program would not run for the entire 2021 compliance period. We believe it is both reasonable to provide more lead time for the NSTOP and that the number of visits under the NSTOP should be adjusted accordingly. Therefore, we are allowing the NSTOP to begin no later than June 1, 2021, as suggested by the commenters. We believe that this will provide enough lead time for fuel manufacturers to register with the program, the independent surveyor to have a plan approved by EPA, and for the independent surveyor to begin visiting fuel manufacturing facilities. We are also only requiring the independent surveyor to visit participating fuel manufacturing facilities one time during the 2021 compliance period instead of the typical two visits. Since our goal is to maximize participation in this voluntary program, we believe providing more lead time and reducing the number of required visits in 2021 will help incentivize fuel manufacturers to participate in the program.

We address other comments related to implementation dates and lead times in Section 4 of the response to comments (RTC) document.

C. Prior Approvals

We are allowing regulated parties with existing approvals under part 80 to maintain those approvals under part 1090. For example, parties registered under part 80 will not need to re-register 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, and also not be consistent with the purposes of regulatory streamlining. However, this action requires that any new requests or updates to approvals currently necessary under part 80 will have to meet the new regulatory requirements of part 1090.

For existing approvals under part 80, regulated parties do not need to update any previously approved submission under part 1090. For example, we have approved alternative E15 labels under part 80. Parties do not need to have these labels reapproved in order to use them under part 1090. One notable exception is for in-line blending waivers for gasoline. As discussed more in Section XIII.G, we are making significant changes to the in-line blending waiver provisions for RFG (mostly to remove provisions related to parameters that will no longer need to be reported) and for CG to make them consistent with the RFG in-line blending waiver provisions. As such, we are requiring resubmission of all in-line blending waiver requests to ensure that they meet the new requirements under part 1090.

Commenters were supportive of our proposed treatment of prior approvals from part 80 under part 1090 and we are finalizing as proposed. We address these comments in Section 4 of the RTC document.

D. Definitions

In part 1090, we are streamlining and updating the definitions contained throughout part 80, as well as adding and removing terms as needed to write the 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 have added additional subparts to part 80 for each new fuels 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 of the same term for the different standards, making 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. Generally, we have tried to avoid having a definition section within individual subparts; however, some infrequently-used terms may still be defined in the context of the regulatory text. We believe this approach helps the regulated community and the public at large to more easily comprehend the regulations.

For the most part, we are simply transferring the existing part 80 definitions into part 1090 with minor changes to specific terms for consistency. However, in some cases, we are redefining or reclassifying key terms in 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 revising the definition of fuels (*e.g.* ''gasoline'' and ''diesel fuel''), which is discussed in Section III.D.3.

For most proposed definitions, commenters were supportive or provided suggestions or requests for clarification regarding specific terms. We address these comments in Section 4 of the RTC document.

1. Fuels, Fuel Additives, and Regulated Blendstocks

In order to improve the clarity and consistency of our regulations, we are changing how we classify products regulated under our fuel quality regulations in part 1090. In part 80, most fuel programs were written as a separate fuel program rather than a single, consolidated fuel quality program. For example, under part 80, subpart I almost exclusively deals with distillate fuels and subpart N deals with gasoline-ethanol blended fuels. Since part 1090 consolidates all fuel quality programs from part 80 (excluding the RFS program) 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 in (*i.e.,* gasoline-fueled, diesel-fueled, or in a vessel subject to Annex VI to the International Convention for the Prevention of Pollution from Ships (''MARPOL Annex VI'') requirements (*e.g.,* vessels that must use Emission Control Area (ECA) or IMO marine fuel)). For gasoline-fueled engines, we not only define the term gasoline (discussed 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 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 produced from transmix continues to be allowed in limited circumstances for certain locomotive and marine applications.

Regarding regulated blendstocks, we have historically not imposed quality specifications on such blendstocks, choosing instead to focus compliance requirements on fuels that are ultimately used in vehicles and engines. However, as the fuels marketplace has continued to evolve, using this structure has become increasingly difficult to accommodate the complexity of fuel manufacturing and distribution practices today. Therefore, we are including alternative provisions, which are currently allowed in 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 imposed standards collectively as ''regulated blendstocks.'' For example, under both part 80 and part 1090, we allow gasoline manufacturers 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 (referred to as ''certified butane'').[8] These certified butane blenders can use these provisions instead of certifying the finished gasoline and having to meet sulfur and benzene annual standards as these provisions are designed to ensure that the amount of sulfur and benzene in the national gasoline pool does not increase as a result of blending these feedstocks. Under part 1090, we are including similar flexibilities as under part 80 for gasoline manufacturers that wish to blend butane that has been certified to meet specifications (differences regarding butane blending between part 80 and part 1090 are discussed in Section V.A.3).

This action also includes the current part 80 specifications for gasoline and diesel additives, mostly unchanged. Except for oxygenates in gasoline, under part 80 and part 1090 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. 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.

We received a comment suggesting that our proposed definition of fuel additive was unnecessarily restrictive on gasoline-ethanol blends. In response, we have revised the part 1090 definition of fuel additive to have the same meaning as ''additive'' under part 79. We further address this comment in Section 6 of the RTC document.

2. Fuel Manufacturers, Regulated Blendstock Producers, and Fuel Additive Manufacturers

We are finalizing the definitions related to parties described as fuel manufacturers, regulated blendstock producers, and fuel additive manufacturers as proposed. In part 80, a refinery is broadly 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.''[9] A refiner is ''any person who owns, leases, operates, controls, or supervises a refinery.''[10] 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 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.

Under part 1090, the term fuel manufacturer describes 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 to make fuel or blending blendstocks into a previously certified fuel to make a new batch of 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 part 79 and the CAA. Under part 1090, we also distinguish further between parties that refine feedstocks to make fuels (more commonly known as ''crude refiners'' or simply ''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.[11] Part 1090 includes requirements specific to the type of fuel manufacturer, and this nomenclature makes it easier for us to describe the specific requirements for each type of fuel manufacturer and for parties to understand what requirements apply specifically to whom. However, while we are modifying the terminology used in part 1090 for these parties, these parties will generally have the same obligations and responsibilities as currently required under part 80.

We are defining producers of regulated blendstocks as regulated blendstock producers. For example, these parties would include certified butane/pentane producers.

As is the case currently under part 79 and part 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 is a blending manufacturer, as the compound added is considered a blendstock and parties that add blendstocks into fuel are considered fuel manufacturers and need to meet all the applicable regulatory requirements. Consistent with part 79, oxygenate blenders that only add oxygenates at levels permissible under

[8] 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 RVP; for RFG, butane blenders cannot blend butane into summer RFG. This provision is not changing in part 1090.

[9] 40 CFR 80.2(h).

[10] 40 CFR 80.2(i).

[11] Under this approach, transmix processors are also considered fuel manufacturers.

CAA section 211(f) continue to be considered oxygenate blenders and not fuel manufacturers.

3. Definition of Fuels

We are finalizing our proposed definitions for fuels (*e.g.,* gasoline, diesel fuel, ECA marine fuel, etc.), largely as proposed. In the NPRM, we outlined a consistent framework for how we would define fuels to help ensure that compliant fuel is ultimately used in vehicles, engines, and equipment. To achieve this goal, we believe that the definition of fuels 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 crude oil refineries still have the most direct impact on 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 a key determinant of the quality of the fuel that actually goes into the vehicle. For example, downstream parties add oxygenates to gasoline (primarily ethanol) and often augment the volume of gasoline through the blending of various blendstocks into PCG to produce new fuels.

To ensure that fuels meet fuel quality standards from the crude oil refinery until they are dispensed into vehicles or engines, in light of the changing fuels marketplace, we believe that any definition of a fuel should contain three elements. First, when a party represents a fuel as meeting EPA's fuel quality standards, such fuel is subject to EPA standards regardless of whether the fuel actually meets the standards. Were this not the case, then anytime a fuel failed to meet EPA standards, we could not hold anyone accountable for failing to meet the standards. In part 1090, we define regulated fuels as anything commonly and commercially known as that particular fuel. This portion of the definition is consistent with the existing definitions of gasoline, diesel fuel, and ECA marine fuel in part 79 and part 80.

The second element of the definition of a fuel is whether a product is used or intended for use as a fuel in a vehicle or engine covered by EPA regulations (*e.g.,* a product that is used or intended for use in vehicles and engines that are designed to use gasoline is gasoline). Since the ultimate purpose of EPA's fuel quality standards is to ensure that compliant fuel is used in vehicles and engines, if a person uses or 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 is gasoline (*i.e.,* a fuel) and is subject to EPA's gasoline standards. The same holds true for diesel fuel or any other regulated fuel. We have used this terminology previously when describing other fuels under part 80, notably in definitions related to motor vehicle diesel fuel [12] and ECA marine fuel.[13]

The third element of the definition of a fuel relates to the physical and chemical characteristics of the fuel. Whether a product is a fuel and therefore subject to our standards and regulatory requirements cannot be solely based on whether a regulated party calls or labels it as a particular fuel. This would create an incentive for parties to simply label products intended for use as fuels by another name to avoid having to meet EPA's fuel quality standards and regulatory requirements. Therefore, when a manufacturer produces a product that is chemically and physically similar to a fuel, the product is a fuel and is subject to EPA's fuel quality standards and regulatory requirements. To address this element, we are specifying that gasoline is any product that meets the voluntary consensus standards body (VCSB) industry specifications for gasoline (ASTM D4814) and diesel fuel is any product that meets industry specifications for diesel fuel (ASTM D975).

In the NPRM, we proposed that certain blendstocks that met ASTM D4814 could be excluded from the definition of gasoline if those blendstocks were not made available as gasoline even though they may otherwise meet the definition of gasoline by meeting ASTM D4814 specifications. We also proposed to apply this same ''made available'' provision to diesel fuel and other fuels covered by part 1090. We explained that ''[s]ince 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 and ECA marine fuel.'' [14]

We received several comments asking for compliance assistance regarding how a company can make sure that EPA will not consider a blendstock that has the same chemical and physical characteristics as a fuel to be a fuel subject to part 1090 standards. In general, we consider any fuel that is stored, sold, or placed into a fuel distribution system that supplies fuel for use in gasoline-fueled vehicles, diesel-fueled vehicles, or marine vessels as being ''made available for use'' in these vehicles or vessels unless the party who produces or distributes the fuel can demonstrate that the fuel was not used, intended for use, or made available for use in these vehicles or vessels.

For example, if a person mixes two distillate blends in a tank and identifies the product as a distillate blend when it loads the product onto a barge that will transfer the fuel to a ECA marine fuel propulsion tank in a marine vessel, we would consider the product to be ECA marine fuel that has been made available for use in a marine vessel and the person would be subject to all of the requirements that apply to fuel manufacturers and distributors under part 1090, including sampling, testing, recordkeeping, and PTD requirements and marine fuel standards. On the other hand, if a person loads a product identified as a distillate blend onto a rail car and has commercial documents showing that the product was sold to a heating oil distributor who only distributes heating oil and the fuel is specifically identified to be used for the sole purpose of heating oil, we would not consider the fuel to be made available for use in a marine vessel.

There are certain products currently in the fuel distribution system that were previously not designated as ''ECA Marine Fuel'' or ''Global Marine Fuel.'' Instead, fuel suppliers have designated these products in accordance with other naming conventions and commonly using terms identified in the International Organization for Standardization (ISO) Petroleum products—Fuels (class F)—Specification of marine fuels (ISO 8217). Examples of these fuel designations include DMX, DMA, DMZ, and DMB (generally referred to by industry as ''marine gas oil'' or ''MGO'') and RMA, RMB, RMD, RME, RMG, and RMK. If a fuel is designated by one of these terms or as a product that is commonly or commercially known to be made available fuel use in marine vessels, we will consider the product to be IMO marine fuel as the fuel has been made available for use in a marine vessel and is subject to all of the requirements for IMO marine fuel in part 1090 (as well as the applicable regulations in part 1043). We also note that intentionally mis-designating a fuel to avoid

[12] See 40 CFR 80.2(y).

[13] See 40 CFR 80.2(ttt).

[14] 85 FR 29034, 29040 (May 14, 2020).

regulatory requirements does not mean those requirements are not applicable nor does it insulate a fuel supplier from potential civil or criminal enforcement.

Since there are many different and complex fuel distribution systems and channels in the U.S., we will evaluate whether a fuel is made available for use in a gasoline-fueled vehicle, diesel-fueled vehicle, or marine vessel on a case-by-case basis.

IV. General Requirements for Regulated Parties

We are including a subpart dedicated to outlining the general regulatory requirements for each regulated party in part 1090 (subpart B). The regulations in part 80 are almost 1,000 pages long, and many regulated parties currently spend a substantial amount of time and resources to comprehend and interpret them or ask EPA staff to identify applicable regulatory requirements.

To make the streamlined regulations more accessible, we are making 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 part 1090 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 will 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 hiring consultants to help them understand their regulatory requirements. Retailers also have a relatively small number of regulatory requirements under part 80 and part 1090. By identifying the generally applicable requirements that apply to all retailers, these small businesses could more easily identify those requirements that apply to them, helping them to more easily comply with EPA's 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 will still need to comply with all applicable requirements contained in part 1090, regardless of whether they are identified for them in subpart B. We cannot predict every possible situation a party may be in within the marketplace now or in the future. Accordingly, regulated parties, as always, should pay careful attention to all the applicable regulatory requirements to ensure compliance.

Commenters were generally supportive of the proposed structure of subpart B and found it helpful to regulated parties in general. We also received comments that included suggested edits to subpart B. We address these comments in Section 5 of the RTC document.

V. Standards

A. Gasoline Standards

1. Overview and Streamlining of Gasoline Program

We are consolidating the various gasoline standards from part 80 into a single subpart in part 1090 (subpart C). We are neither changing the gasoline lead, phosphorous, sulfur, benzene or RVP standards, nor modifying the standards for oxygenates (including DFE), certified ethanol denaturant, gasoline additives, and standards for certified butane and certified pentane. These standards are simply being moved and consolidated into subpart C.

To further streamline the gasoline program, we are altering 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 will 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 translating the RFG standard from the demonstration of the VOC performance standard via the Complex Model into an equivalent maximum RVP per-gallon standard, which allows us to greatly simplify the compliance demonstration requirements for RFG. Of all the provisions being finalized, this is the key provision enabling considerable streamlining of the existing gasoline regulations.

Second, we are consolidating the two grades of butane and 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 greatly simplifies the registration and reporting of activities related to blending certified butane and certified pentane.

Finally, we are establishing 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.[15]

2. RFG 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 volatility of 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: (1) Replacing the existing compliance mechanism used for RFG batch certification—the Complex Model—with a summer maximum RVP per-gallon standard (''RVP standard''); (2) applying that same single RVP standard to all RFG nationwide; (3) provide greater flexibility for blending of oxygenates (*e.g.,* ethanol and isobutanol) and E0 in RFG areas; and (4) removing several other restrictions that currently create a distinction without a difference between RFG and CG.

We intend these changes to maintain the stringency of all standards associated with RFG while alleviating unnecessary compliance burden. We acknowledge that the CAA requires the existence of RFG in specified nonattainment areas [16] and certification procedures to certify RFG as complying with the requirements.[17] This action will simplify and translate the previously established requirements while still maintaining the same level of VOC emissions reductions as currently required. This will be accomplished by translating the current VOC emissions reductions demonstrated through the Complex Model into an RVP standard that will be used to demonstrate RFG

[15] The proposed changes to the transmix provisions for gasoline and diesel fuel are addressed in Section XIII.E.

[16] CAA section 211(k)(1).

[17] CAA section 211(k)(4)(A).

VOC compliance in lieu of the Complex Model.[18]

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 largely through the use of an RVP standard in combination with the previously established sulfur standard.

The RFG RVP standard of 7.4 psi was specifically chosen in order to maintain the summer VOC performance required by the statute,[19] and this RVP is currently observed in the RFG 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.b. This consolidation of RFG VOC Regions, along with other changes in this action, will 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 action are potentially wide reaching as it could create opportunities for broader availability of fuels and reduced consumer costs. By having a single RVP standard for RFG, in situations of fuel shortage in RFG areas during the summer, 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 (*e.g.,* E0 or isobutanol blends) 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, using the downstream gasoline before oxygenate blending (BOB) recertification provisions discussed in Section VII.G, it will be easier for distributors to provide ethanol-free gasoline to consumers in these areas.

a. 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, we proposed that, under part 1090, any summer RFG batch meeting an RVP standard of 7.4 psi would be deemed compliant with the RFG VOC emission performance reduction standard. Many commenters were supportive of this approach, and we are finalizing these regulations as proposed.[20] [21] Along with RVP, benzene concentration for MSAT2 compliance, and sulfur content for Tier 3 compliance will also be reported to EPA. Thus, all three of the emission reduction standards for RFG will be covered by just three parameters: RVP, benzene, and sulfur. This will reduce the compliance and reporting burden for gasoline manufacturers by reducing the number of parameters they need to test and report from 11 to as few as 3 in the summer.[22] [23]

Our intent in translating the VOC performance standards into a maximum RVP per-gallon standard is to both ensure that the emission reduction targets for RFG and the current emissions performance will continue to be achieved. In determining the RFG 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 7.4 psi RVP standard for RFG will 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 national fuels survey program (NFSP). Continued adherence to the RFG VOC emission performance reduction standard will be monitored through samples collected from RFG areas as part of the NFSP. This oversite function will help ensure that the emission reductions the Complex Model was intended to certify at the fuel manufacturing facility gate are being maintained in use.

b. Consolidation of RFG VOC Control Regions

Translating the VOC emissions performance standard into a summer RVP standard enables EPA to simplify the RFG program significantly. Additionally, the creation of a single summer RVP standard for all RFG areas further simplifies the RFG program and automatically consolidates the VOC regions as required under section 1504(c) of EPAct, which directs EPA to revise the RFG regulations to consolidate the regulations for the VOC-Control Regions by eliminating the less stringent requirements.[24]

[18] Currently, refiners use the Complex Model to demonstrate compliance with the RFG provisions. Under part 1090, refiners are required to instead demonstrate compliance by testing the RVP of the fuel, along with benzene and sulfur as currently required under part 80.

[19] 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.'' Our 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).

[20] 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.

[21] The process and rationale for the RFG maximum RVP per-gallon standard of 7.4 psi discussed in ''History, Methods, and Underlying Data Support for RFG Standard Translation to RVP,'' available in the docket for this action.

[22] As discussed in Sections VIII and IX, blending manufacturers will need to sample, test, and report for additional fuel parameters.

[23] Typically, under part 1090, gasoline manufacturers must sample for sulfur, benzene, and, for summer gasoline, RVP for batch certification. In cases where gasoline manufacturers are certifying a batch of gasoline that has already had oxygenate added (not including a hand blend), the manufacturer must also test for oxygenates. In addition, blending manufacturers must also test batches of gasoline for distillation parameters. Therefore, a gasoline manufacturer must test between 3 and 5 parameters under part 1090.

[24] 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–

Continued

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 RFG areas. The summertime RFG VOC emission performance standard for RFG VOC Region 2 is slightly less stringent than RFG VOC Region 1. To date, EPA had not taken action to consolidate the VOC regions as directed by EPAct. However, the creation of a single RFG RVP standard provided both an opportunity and a mechanism by which to act on this requirement. A benefit of this consolidation will be the increased fungibility of RFG amongst historically distinct VOC-control regions. Furthermore, we find that the EPAct language provides EPA with an additional source of authority to take this final action to translate the VOC performance standard into a single RVP standard.

c. Additional Changes Related to RFG

We are also finalizing regulations intended to allow for greater compliance flexibility and increased gasoline fungibility for the RFG program. Specifically, as discussed in Section VIII.G, we are finalizing 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 comingling RFG and CG in the winter exists.

To address this situation, we are finalizing provisions to allow all winter gasoline to be used in RFG areas without recertification. Distributors of gasoline will be allowed to designate winter gasolines without recertification as RFG or CG to comport with state or pipeline specifications, which may require those distinctions.

All comments received on the proposed RFG RVP standard of 7.4 psi, consolidation of the VOC control regions, and improved fungibility provisions for RFG were supportive. We did, however, we receive comments asking for minor edits to and clarifications of the regulatory requirements for RFG under part 1090. We address these comments in Section 6 of the RTC document.

3. Certified Butane and Pentane

We are streamlining the provisions for gasoline blending manufacturers that blend butane and pentane of certified quality (certified butane and certified pentane, respectively) into PCG.[25] 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 basic approach is maintained in part 1090.

Part 80 has two grades of butane and pentane (commercial and noncommercial) that can be used by gasoline blender manufacturers under these provisions. We are combining these grades into single grades of ''certified butane'' and ''certified pentane.'' Consolidating the grades of butane and pentane allows for streamlined compliance demonstrations for certified butane and certified pentane blenders to produce gasoline using certified butane and certified pentane.

The part 80 standards for commercial and noncommercial grades of butane and pentane contain specifications on the maximum sulfur, benzene, olefin, and aromatics content. Consistent with the changes to RFG certification discussed in Section V.A.2, we are removing the maximum olefin and aromatics standards from the specifications for certified butane and certified pentane. Under part 1090, both certified butane and certified pentane will continue to 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 under part 80. 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 and higher carbon number hydrocarbons specification.[26] 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. In part 1090, we are removing the standard on C6 and higher hydrocarbon content for certified pentane given that compliance with the 95 volume percent pentane purity specification ensures that no more than 5 volume percent C6 and higher hydrocarbons are present. We did not receive any adverse comments to this proposal for certified pentane standards, and so we are finalizing the certified pentane standards as proposed.

Unlike the part 80 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 removal of the maximum olefin and aromatics specifications for certified butane, it is appropriate to impose controls on the purity of certified butane that are consistent with the purity specification for certified pentane. In the NPRM, we proposed a 92 volume percent purity specification for certified butane. While slightly lower than the 95 volume percent purity specification for certified pentane, we argued that the slightly lower standard would not result in increased emissions from the use of certified butane compared to a 95 volume percent purity specification and would allow necessary flexibility to industry. We received several comments suggesting that we should impose a lower certified butane purity standard. Commenters suggested a range of options from 80 volume percent to 90 volume percent. Most commenters suggested that a purity specification of 85 volume percent would allow for a high-quality product without disrupting existing butane blending practices. We agree with these comments and are therefore finalizing an 85 volume percent purity specification for certified butane.

We are also simplifying the quality assurance requirements for certified butane and certified 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. The sampling and testing frequency for butane received from each butane supplier under part 80 is one sample for every 500,000 gallons, or one

R–13–002. Assessment and Standards Division, Ann Arbor, MI. April 2013.

[25] 40 CFR 80.82 and 80.85, respectively.

[26] C6 refers to a hydrocarbon molecule that contains six carbon atoms. Pentane has 5 hydrocarbons (*i.e.,* it is C5).

sample every three months, whichever is more frequent. The sampling and testing frequency for commercial grade pentane received from each pentane supplier under part 80 is once for every 350,000 gallons of pentane received, or one sample every three months, whichever is more frequent. Under Part 80, noncommercial-grade pentane is 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, under part 1090 we are requiring the same sampling and testing frequency for certified butane and certified pentane to be once every 500,000 gallons of butane or pentane received, or one sample every three months, whichever is more frequent. More frequent sampling and testing is not needed for certified pentane versus certified butane, given that they are subject to similar standards. Existing registration requirements for certified pentane producers will help to mitigate concerns that pentane manufacturing processes may increase concentration of high boiling range hydrocarbons (such as C7–C20 hydrocarbons).[27] We received no adverse comments on this aspect of the proposal, and so we are finalizing these provisions as proposed.

4. State and Local Fuel Standards

a. Overview

As proposed, we have transferred and consolidated the part 80 regulations that relate to RVP and RFG requirements in 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 finalizing 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 finalizing procedures for states that request a relaxation of the federal RVP standard of 7.8 psi. These procedures are similar to the existing procedures used for RFG opt-out by states. We are not finalizing any regulatory revisions for current fuel programs that apply in several states. The following sections detail the changes we are finalizing.

We are also announcing that an updated boutique fuel list is currently posted on our website.[28] 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.[29] Several fuels have ceased to be included in SIPs since the boutique fuel list was originally published in 2006.[30] 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

As proposed, we have transferred summer gasoline requirements related to RVP standards that are currently in part 80 to part 1090. Summer gasoline for use in the continental U.S. must comply with either the federal RVP standard of 9.0 psi or the more stringent RVP standard of 7.8 psi, unless it is either for use in a RFG covered area, is subject to California's gasoline regulations, or EPA has waived preemption and approved a state request to adopt a more stringent RVP standard into a SIP.[31] [32] [33] Part 1090 simplifies and clarifies the regulatory text previously located in 40 CFR 80.27(a) and 80.70, and does not change the current RFG and summer gasoline standards nationwide, and requires all gasoline designated as summer gasoline or located at any location in the U.S. during the summer season to meet applicable RVP per-gallon standards. The regulations include a limited exception to facilitate the movement and storage of gasoline that does not meet the applicable RVP standards if it is locked down and is not delivered to any retail station or wholesale purchase consumer. This exception is primarily designed to accommodate the transition from summer to winter gasoline and allow the transportation and storage of higher RVP fuel through areas that are subject to more stringent standards. The exception places the burden on the regulated community to demonstrate that the gasoline is properly designated and isolated and is not delivered to any retail station or wholesale purchaser consumers during a time or place prohibited by the regulations.

c. Reformatting the List of Areas Where the Federal 7.8 psi RVP Standard Applies

As proposed, we have transferred to part 1090 the current RVP standards in 40 CFR 80.27(a)(2), which previously set out the current federal RVP standards. Areas subject to the federal 7.8 psi RVP standard are listed in a table in 40 CFR 1090.215(a)(1), describing the geographic areas subject to the 7.8 psi RVP standard. Part 1090 specifies that any gasoline that is not subject to a lower RVP standard is subject to the federal 9.0 psi RVP standard. We did not propose and therefore are not finalizing any changes or revisions to applicable RVP standards. Specifically, we:

- Removed the regulatory text in 40 CFR 80.27(a)(1) because it was outdated and has not applied since 1991.
- Replaced the regulatory text, table, and footnotes that were 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 standard for summer gasoline currently applies.

The table in 40 CFR 80.27(a)(2) dates back to the initial one-hour ozone NAAQS and is overly complex and has caused confusion among states and industry. The new table in 40 CFR 1090.215(a)(1) includes the name of the nonattainment area and the county or counties in the area where the federal 7.8 psi RVP standard applies. The new table under part 1090 also includes a description of the boundaries for areas that include partial counties where RVP standards are currently in effect. Under 40 CFR 80.27(a)(2), interested parties had to search 40 CFR part 81 in order to identify these specific boundaries of the area where the 7.8 psi RVP standard applies. As previously noted, this action does not change any existing requirements.

d. Reformatting RFG Applicability and Covered Areas

As proposed, we have transferred part 80 requirements relating to RFG to part 1090, and we have reformatted how the information on RFG covered areas is

[27] 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 of concern with respect to increased emissions.

[28] See *http://www.epa.gov/gasoline-standards/state-fuels.*

[29] See CAA section 211(c)(4)(C)(v)(III).

[30] See 71 FR 78195 (December 28, 2006).

[31] Some states where the federal 7.8 psi RVP standard is required have chosen instead to apply 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.

[32] California has set requirements for gasoline sold throughout the entire state (''California gasoline''), 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.

[33] In the absence of California's RFG regulation, either federal RVP standards or RFG would apply in California. Some areas would be RFG covered areas because either they were among the original nine RFG covered areas or they were reclassified to Severe nonattainment for an ozone National Ambient Air Quality Standard (NAAQS). See CAA section 211(k)(10)(D).

presented. Specifically, in 40 CFR 1090.285 we present the description of RFG covered areas in a table format and have grouped the covered areas by the statutory provision under which the area became a covered area. The following are four requirements under which an area could have become an RFG 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 nation's 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 RFG.

We have also transferred the existing regulatory processes by which an area may become an RFG covered area in the future to part 1090. These processes apply 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 an RFG covered area.

We also now include two additional California areas on the list of RFG covered areas in part 1090 because the areas became RFG covered areas when they were reclassified as Severe ozone nonattainment areas.[34] The two areas are the Sacramento Metro area and the San Joaquin Valley area.[35] 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 continued applicability of California's regulations that require the sale of California gasoline in these areas, but should California's regulations no longer apply in the future, EPA's RFG regulations would likely still apply in keeping with the CAA.

e. Continuation of 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 EPA's opt-out regulations. We also included regulatory text in 40 CFR 80.70(m),[36] parts of which have become outdated and unnecessary because they were specific to the transition from the 1-hour ozone NAAQS to the 1997 ozone NAAQS, both of which have since been revoked.

As proposed, in part 1090 we are maintaining and clarifying our intention and existing practice with regard to applicable RFG requirements. Specifically, 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)). Requiring the continued implementation of RFG in all covered areas is consistent with how the RFG program has been implemented during the transitions to the 1997, 2008, and 2015 ozone NAAQS. Part 1090 includes procedures for either removing a prohibition on or opting out of RFG, consistent with CAA requirements; thus, part 1090 continues to allow states to revise RFG requirements under certain circumstances.

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 areas where RFG use was mandated pursuant to CAA section 211(k)(10)(D) (*i.e.,* the areas with the nine highest 1-hour ozone design values from 1987–1989 or areas reclassified to Severe for an ozone NAAQS).[37]

As proposed, we are finalizing a new provision in part 1090 that will allow a 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 40 CFR 1090.290(d), 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 of the request 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 either be redesignated to attainment for the 2015 ozone NAAQS (if it had been designated as nonattainment for that NAAQS) or be designated as an attainment area for the 2015 ozone NAAQS. On the other hand, if the area is designated as an attainment area for the most stringent ozone NAAQS in effect, the area would have to be redesignated to attainment for the prior ozone NAAQS before the RFG program could be removed. For example, 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 a nonattainment area that has been redesignated to attainment for the 2015 NAAQS to be eligible for consideration for removal of the RFG program. In either case, we are requiring that any request to remove the RFG requirements must include an approved maintenance plan that demonstrates maintenance of the ozone NAAQS throughout the period addressed by the maintenance plan without the emission reductions from the RFG program. Additionally, we are requiring that a state must also demonstrate that the removal of the requirement for the 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.[38]

States with current mandatory RFG covered areas may seek to remove the requirement for RFG 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 have the ability to use their 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 over 30 years ago or were reclassified as Severe for a prior ozone NAAQS. This approach is premised on our view that once a covered area attains the most stringent ozone NAAQS, states should

[34] See CAA section 211(k)(10)(D).

[35] The Sacramento Metro area was reclassified as a severe ozone nonattainment area on June 1, 1995, and became an 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 an RFG covered area on December 10, 2002. See 66 FR 56476 (November 8, 2001).

[36] See 70 FR 71684–9 (November 29, 2005).

[37] See 70 FR 71687 (November 29, 2005).

[38] See CAA section 110(*l*).

be able to determine whether an emission reduction strategy (in this case RFG) should either continue or be removed as long the state 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 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). The opt-out procedures, which were established in 1996 and 1997, are not being revised in this action except for transferring them to part 1090, removing obsolete regulatory text (*e.g.,* removing requirements that applied for specific periods of time that are now in the past), and making minor clarifications.

A commenter stated that Congress created mandatory RFG covered areas, and it is up to Congress to eliminate this provision. This commenter believed that EPA does not have the authority to remove the RFG program for a mandatory RFG area created by Congress and the statute is unambiguous regarding this matter. We disagree and have concluded that there is legal authority to support removal of RFG requirements in mandatory RFG areas as long as the criteria established in part 1090 are met. This comment is addressed in more detail in Section 6 of the RTC document.

Another commenter asked whether the RFG opt-out procedures apply to both opt-in and mandatory areas because the proposed regulations could be read to allow only opt-in areas to request removal of an RFG program from a portion of the covered area. The commenter also sought clarification on whether a mandatory RFG area must be in attainment for all prior ozone NAAQS, or only the immediately prior ozone NAAQS (in addition to the most stringent NAAQS) in order to request removal of the RFG requirement.

As proposed, the RFG opt-out regulations could be read to draw a distinction between opt-in areas and mandatory areas under CAA section 211(k)(10)(D). We intended that these opt-out regulations would apply to both opt-in areas and mandatory areas in the same way. In response to this comment, we have revised the RFG opt-out procedures to clarify that the provisions apply to both opt-in areas and mandatory areas in the same manner. Specifically, both opt-in areas and mandatory areas can have the RFG requirement removed from either the entire area or from a portion of the area, provided that the relevant criteria and procedures are followed.

With respect to the request for clarification regarding whether a mandatory RFG area must be in attainment for all prior ozone NAAQS, mandatory RFG areas will remain RFG covered areas until the criteria in part 1090 are met, and the state follows the procedures to have the requirements to sell RFG removed, the EPA Regional Office approves the state's SIP revision and CAA section 110(*l*) demonstration, and EPA establishes an effective date for the removal of the area. Such an area would have to attain the most stringent ozone NAAQS in effect at the time. The state would have to revise any relevant CAA section 175A maintenance plan and comply with CAA section 110(*l*) non-interference requirements. Two examples are provided in the following paragraphs.

One example is for a state seeking removal of the RFG program from a mandatory RFG area that was initially designated as nonattainment for the most stringent ozone NAAQS in effect at the time of the request for the removal (*e.g.,* currently the 2015 ozone NAAQS) and the area has been redesignated to attainment with an approved CAA section 175A maintenance plan for that NAAQS. In this case, the state need only address that most stringent ozone NAAQS by revising the approved CAA section 175A maintenance plan for that ozone NAAQS to show continued maintenance of that ozone NAAQS without the emissions reductions from RFG and comply with CAA section 110(*l*) non-interference requirements.

Another example is if a state is seeking removal of the RFG program from a mandatory RFG area that was initially designated as an attainment area for the most stringent ozone NAAQS in effect. In this case, it needs to address the prior ozone NAAQS by revising the CAA section 175A maintenance plan for that area for the prior ozone NAAQS (*i.e.,* currently the 2008 ozone NAAQS) to show continued maintenance of that ozone NAAQS without the emissions reductions from RFG and comply with CAA section 110(*l*) non-interference requirements. We also expect a state seeking the removal of the RFG requirement in a mandatory area to briefly discuss its air quality status with respect to the 1-hour ozone NAAQS (*i.e.,* the area's current design value) because all mandatory areas under CAA section 211(k)(10)(D) became mandatory areas due the severity of the 1-hour ozone NAAQS problem in these areas.

g. Providing Streamlined Procedures for Areas Relaxing the Federal 7.8 psi RVP Standard

As proposed, we are finalizing 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. Part 1090 provides procedures similar to those that are currently used when states opt out of the RFG program.[39]

The current federal 7.8 psi RVP standard took effect in 1992 and was initially required in certain 1-hour ozone NAAQS nonattainment areas. States have had the ability to request relaxation of this RVP standard provided that all CAA requirements are fulfilled (*e.g.,* revising approved SIPs as necessary and EPA's approval of those SIP revisions and approval of a CAA section 110(*l*) non-interference demonstration). 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.[40] 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 standard continues to apply.

Under our previous regulations, the process for accomplishing a 7.8 psi RVP relaxation required two EPA approval actions before a state's request could become effective. First, the EPA Regional Office needed to approve a state's revision to an area's SIP, such as a maintenance plan, for the relevant ozone NAAQS and a CAA section 110(*l*) non-interference demonstration. After the EPA Regional Office rulemaking was completed, a second rulemaking by EPA Headquarters was necessary to remove the subject area(s) from the federal 7.8 psi RVP regulations in 40 CFR

[39] 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.

[40] For more information on EPA's actions, see *www.epa.gov/gasoline-standards/federal-gasoline-regulations.*

80.27(a)(2).[41] The process involving both of these approval actions before a state's request could become effective was cumbersome and time consuming given the number of linear steps involved. There was also an element of confusion and uncertainty to states, local businesses, industry, and the public concerning the effective date of an RVP relaxation.

Based on our experience since 2014, we proposed that the current RFG opt-out regulatory procedures would provide a better model for considering and approving state requests to relax the federal 7.8 psi RVP standard. Thus, the part 1090 regulations for relaxing the federal 7.8 psi RVP standard mirror the RFG opt-out procedures, and are as follows:

- The governor of the state, or the governor's designee, requests in writing that EPA relax the federal 7.8 psi RVP standard.
- The state is 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 standard 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 EPA Regional Office's action is complete, EPA Headquarters would establish an effective date for the relaxation, which would be no less than 90 days after the effective date of the EPA Regional Office's approval. We then 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 standard continues to apply (*i.e.,* from the list of areas in part 1090). We have concluded that notice-and-comment rulemaking to revise the list of areas in part 1090 is not necessary for relaxation actions to become effective because it merely codifies a change that has been made through a process that is included in our regulations and is thus, merely administrative in nature.

This process will eliminate the need for EPA to complete a notice-and-comment rulemaking to update the list of areas in part 1090 each time we act on a request to relax a federal 7.8 psi RVP standard to remove the subject area from the list of areas subject to that standard. Under the process in part 1090, which is similar to the RFG opt-out procedures, the effective date of the federal 7.8 psi RVP relaxation would be known shortly after the EPA Regional Office's rulemaking on the state's SIP revision and CAA section 110(*l*) non-interference demonstration becomes effective. Using similar procedures for acting on state requests to change either federal 7.8 psi RVP or RFG programs will also avoid unnecessary confusion and still continue to provide the same level of environmental protection. Under both the former part 80 regulations and the current part 1090 regulations, 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 7.8 psi RVP fuel and comply with the CAA's non-interference requirements.[42] Further, we will continue to act on such SIP revisions and CAA section 110(*l*) non-interference demonstrations through notice-and-comment rulemaking. Finally, this process, which streamlines the RVP relaxation program, results in the conservation of limited government resources and brings certainty for states, the public, and gasoline suppliers as to when a state's request to relax RVP would take effect.

h. Transitioning From RFG or a Boutique Fuel Program to the Federal 9.0 psi RVP Standard in Certain States

In this action we are providing information for states that decide to either opt out of RFG or remove a state SIP fuel rule that regulates gasoline RVP (*i.e.,* a boutique fuel). Specifically, a state in its SIP revision (*e.g.,* maintenance plan revision) may request that EPA apply the federal 9.0 psi RVP standard rather than the federal 7.8 psi RVP standard.[43] 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.[44] 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 in lieu of a more restrictive standard. States have previously accomplished this goal by first submitting a SIP revision (*e.g.,* a maintenance plan revision) that removes the state fuel RVP standard or opts out of the RFG program and applies the federal 7.8 psi RVP standard and addresses CAA section 110(*l*) non-interference demonstration requirements. Later, such states would submit 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 in this action to ensure that states are aware that they can accomplish the goal of relaxing the federal RVP standard to 9.0 psi through one SIP revision as long as the associated SIP revision meets 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 that SIP revision, and one EPA action to update the lists areas subject to the specific gasoline standards will conserve state and federal resources.

Allowing the transition to the federal 9.0 psi RVP standard 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 when gasoline that complies with the federal 9.0 psi RVP standard is sold in the area. This approach also provides fuel suppliers with certainty and stability. Transitioning directly to the 9.0 psi RVP standard through one SIP revision, rather than accomplishing this through two SIP revisions as has occurred in the past, avoids the need for fuel suppliers to supply the area with 7.8 psi RVP gasoline for a short period of time, only to ultimately switch to supplying gasoline that meets the 9.0 psi RVP standard.

[41] 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. See, *e.g.,* the RVP relaxation for several parishes in Louisiana (82 FR 60886, December 26, 2017).

[42] See CAA section 110(l).

[43] In 1990 and 1991, 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. See June 11, 1990 (55 FR 23658) and December 12, 1991 (56 FR 64704).

[44] See CAA section 110(l).

We note, however, that if such a state wants EPA to apply the federal 7.8 psi RVP standard, 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 standard. In such a case, we 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 State Fuels website.[45] 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 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 December 28, 2006.[46]

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.[47] Since the original list was published, several fuels have been removed from approved SIPs and have thus ceased to exist in SIPs.[48] In addition to our aforementioned website, we are providing an updated list of boutique fuels that includes all of the boutique fuels that are currently in approved SIPs in Table V.4.h–1 below. 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.4.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[49].
	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[50].

*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, it was not listed in part 80 among the requirements for fuel.[51] As part of our effort to consolidate fuels compliance requirements and make it easier for regulated parties to understand their obligations, we are finalizing a requirement in part 1090 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).[52]

EPA has issued two coexisting definitions of substantially similar for gasoline, one in 2008[53] and one in 2019,[54] and several CAA section 211(f)(4) waivers. The part 1090 regulations refer to the statutory provisions (CAA section 211(f)(1) and (4)). EPA has issued interpretative rules on the meaning of ''substantially similar'' under this provision.[55] EPA has also issued many CAA section 211(f)(4) waivers from the substantially similar provision, including, but not limited to the E10 (''gasohol'') waiver and the Octamix waiver.[56] Fuel and fuel additive manufacturers are expected to comply with the parameters associated with the definitions of ''substantially similar'' when introducing gasoline or gasoline additives into commerce under CAA section 211(f)(1). Fuel and fuel additive manufacturers are expected to comply with any conditions associated with a CAA section 211(f)(4) waiver when introducing gasoline or gasoline additives into commerce under a waiver.

We have made some modifications to the ''substantially similar'' requirement in response to comments received by stakeholders. We have also added the ''substantially similar'' requirement to the diesel standards in this final rule in order to comprehensively cover the requirements imposed by CAA section 211(f)(1) and (f)(4) as they pertain to gasoline and diesel fuels. We further address these comments in Section 6 of the RTC document.

[45] See *https://www.epa.gov/gasoline-standards/state-fuels.*

[46] See 71 FR 78192 (December 28, 2006).

[47] See CAA section 211(c)(4)(C)(v)(III).

[48] 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.

[49] 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).

[50] 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).

[51] The FFARs 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).

[52] Our authority to codify the ''substantially similar'' requirement in regulations is explained at 81 FR 80877–78 (November 16, 2016).

[53] See 73 FR 22277 (April 25, 2008).

[54] See 84 FR 26980 (June 10, 2019).

[55] See 73 FR 22277 (April 25, 2008) and 84 FR 26980 (June 10, 2019).

[56] See 44 FR 20777 (April 6, 1979), Octamix Waiver, 53 FR 3636 (February 8, 1988).

B. Diesel Fuel

1. Overview and Streamlining of Diesel Fuel Program

Similar to our approach for the gasoline standards, we are consolidating the diesel fuel standards into a single subpart in part 1090 (subpart D). We are not making 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. However, we are removing expired provisions that were needed to support the phase-in of the current diesel fuel sulfur program. The phase-in period was completed in 2014; however, these now expired phase-in provisions are imbedded throughout the diesel fuel program regulations in part 80, 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 also making revisions to the part 80 regulations in moving them to part 1090 as discussed in the following sections. First, we are removing the requirement that motor vehicle diesel fuel be free of red dye because we believe this requirement is no longer necessary to evaluate compliance with the diesel sulfur standards. Second, we are streamlining the requirements that pertain to importation of diesel fuel that does not meet EPA standards. Third, we are removing the requirement for ECA marine fuel distributors and associated requirements to include a registration number on PTDs. Finally, we are streamlining the means for downstream parties to redesignate heating oil, kerosene, or jet fuel as ULSD.

We expect that these changes will simplify the diesel fuel programs, resulting in reduced burden associated with demonstrating compliance with the 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

Under the Internal Revenue Code, non-road, locomotive, and marine (NRLM) diesel fuel, heating oil, and exempt highway diesel fuel [57] 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. Consequently, 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.[58]

However, as other distillate fuels have become subject to the same 15 ppm sulfur standard that applies to highway diesel fuel, the presence of red dye has ceased to be a useful indicator of sulfur noncompliance. With the completion of the phase-in of EPA's 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 also currently subject to a 15 ppm standard.[59] Therefore, we believe that the requirement that red dye should not be present in motor vehicle diesel fuel no longer provides any meaningful added assurance of compliance with ULSD standards. Rather, the existence of this requirement now just 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 as specified under CAA section 211(c)(4)(C)(ii). State authorities are currently required to request a waiver from both 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.

Commenters were generally supportive of removing the red-dye requirement. Consequently, we are removing the EPA requirement that motor vehicle diesel fuel must be free from visual evidence of red dye as proposed.[60] This change does 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. However, EPA will continue to coordinate with IRS staff in cases where supply issues arise if needed.

3. Importation of Off Spec Diesel Fuel

We are replacing the provisions for the importation of diesel fuel treated as blendstock (DTAB) under part 80 [61] with a streamlined procedure to handle imported off-spec diesel fuel. 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 may 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 part 1090, the importer is required to offload the imported diesel fuel into one or more shore tanks containing diesel fuel, 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.

We received no adverse comments to our proposed streamlining of the DTAB provisions and therefore we are finalizing these provisions as proposed.

4. MARPOL Annex VI Marine Fuel Standards

In this action, we are mostly transposing 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 MARPOL Annex VI. The U.S. ratified MARPOL Annex VI and became a Party to this Protocol effective January 2009. MARPOL Annex VI requires marine vessels operating globally to use fuel that meets the 0.50

[57] Such as diesel fuel used in school buses.

[58] See 40 CFR 80.520(b).

[59] 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.*

[60] See 40 CFR 80.520(b)(1).

[61] See 40 CFR 80.512.

percent sulfur standard starting January 1, 2020 (''global marine fuel''). The MARPOL Annex VI standard is 0.10 percent sulfur for fuel used in vessels operating in designated ECAs.[62]

In a separate action, we modified the 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.[63] We are incorporating those provisions into part 1090 with minor changes to be consistent with the new 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 manufacturer to the point of transfer to a vessel were required to register with EPA and include this registration number on PTDs.[64] Distributors of other 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.[65] The majority of these requirements gradually expired with the phase-out of the ULSD program's small refiner and early credit provisions that ended in 2014, which had allowed the production of limited volumes of 500 ppm highway diesel fuel. Beginning in 2014, the only fuel distributors still required to register with EPA were those that handle ECA marine fuel and 500 ppm LM diesel fuel produced by transmix processors.[66]

We believe that the benefit associated with having ECA marine fuel distributors register with EPA does not outweigh the burdens associated with this requirement. All comments received on this issue supported the elimination of the registration requirement for ECA marine fuel distributors, and we are finalizing its removal as proposed.

5. Heating Oil, Kerosene, and Jet Fuel

When we first established the diesel fuel sulfur program under part 80, it required only on-highway or motor vehicle diesel fuel to meet the 15 ppm sulfur standard. In order to implement and enforce this standard and avoid the contamination of ULSD with higher sulfur distillate fuels (which at the time were non-road diesel, heating oil, kerosene, and jet fuel), it required that we include a number of regulatory provision to designate, segregate, and label distillate fuels. Now the 15 ppm sulfur standard to all diesel fuel (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 are no longer serving any purpose. However, the provisions have remained in place under part 80 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.).

In the NPRM, we proposed 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 provisions, downstream parties may rely on documentation from pipelines or fuel manufacturers that the heating oil, kerosene, or jet fuel was certified to meet the 15 ppm sulfur standard and cetane/aromatics specifications to fungibly transport, store, and dispense all 15 ppm sulfur distillate fuels downstream. We also proposed to 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.

Comments were supportive of the proposed provisions for the redesignation of distillate fuels certified to meet the ULSD standards and we are finalizing these provisions as proposed. We believe that these provisions will maximize the fungibility of distillate fuels, resulting in substantially reduced distributional costs and greater efficiency in the fuels market.

6. Downstream Testing Adjustment for ULSD

In part 80 there is a 2-ppm sulfur downstream testing tolerance for ULSD.[67] This was not carried over into the proposed part 1090 regulations as diesel sulfur levels are typically much lower than the 15 ppm standard and the opportunities for contamination in the distribution system have been reduced with the establishment of sulfur limits on all gasoline, diesel fuel, and most heating oil. We received a number of comments highlighting that this adjustment remains necessary to account for test variability in the measurement of sulfur in ULSD. Based on these comments, we are including the 2-ppm sulfur downstream testing adjustment for ULSD in part 1090. We believe that the variability in the most commonly used test methods for measuring sulfur in ULSD appears to continue to necessitate the adjustment. In the future, as improvements are made to the measurement of sulfur in ULSD, we may revisit the need for this testing adjustment.

VI. Exemptions, Hardships, and Special Provisions

A. Exemptions

We are transferring provisions that exempt fuels from applicable standards that are currently contained in part 80 to part 1090. We are making minor revisions for purposes of modernizing these exemptions, as well as removing obsolete exemption provisions. Any exemptions that were granted under part 80 will remain in effect with their original conditions as applicable under part 1090. As a result of moving these provisions to part 1090, instead of being scattered through various subparts as is the current practice in part 80, they will be consolidated into a single subpart (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 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) under part 1090.

We are not making any revisions to exemptions nor the related requirements that apply to fuels used for national security and military purposes, temporary research and development

[62] Designated ECAs 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.

[63] See 84 FR 69335 (December 18, 2019).

[64] See 40 CFR 80.597(d)(3).

[65] See 40 CFR 80.597 regarding the distributor registration requirements and 40 CFR 80.590(a)(6)(i) for the associated PTD requirements.

[66] The production of 500 ppm LM diesel fuel is discussed in Section XIII.E.4.

[67] See 40 CFR 80.580(d).

(R&D), racing, and aviation. Similarly, we are not changing the exemption that applies to fuels for use 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 will also continue to be exempt from the federal volatility regulations.

We are, however, making minor revisions to these exemptions for consistency and as a result of consolidating the various part 80 exemptions, and to modernize the exemption provisions. First, we are including language that imposes conditions on parties operating under an 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 requested 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. However, we received no comments on this topic and therefore are finalizing the R&D exemption provisions as proposed. We address comments related to the R&D exemption in Section 9 of the RTC document.

Second, we are allowing 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 part 1090, fuel additives and regulated blendstocks will now be exempt from applicable requirements if certain conditions are met. For example, the military use exemption now explicitly exempts fuels, fuel additives and regulated blendstocks used in either military vehicles or in support of military operations.

Third, we are finalizing as proposed the regulatory provision to prevent contamination of motor vehicle fuels by exempt fuels, such as racing and aviation gasoline containing lead additives, at 40 CFR 1090.615(c) (which is carried over from part 80). This regulatory provision requires the segregation of exempt fuels from production through consumption. We had also proposed a new provision at 40 CFR 1090.615(e) that was also designed to shore up protection against contamination of motor vehicle fuels during distribution by tanker trucks. For example, when a tanker truck carrying exempt racing gasoline or aviation gasoline is later used to transport non-exempt gasoline, residual exempt gasoline could remain in the tanker truck and contaminate the non-exempt gasoline. We referred regulated parties to follow established voluntary consensus-based standards for managing the transportation of both exempt and non-exempt fuels in the same transportation vessel.[68]

A commenter requested that we remove the proposed examples that referenced industry guidance from the regulations because these standards can change over time. In response to those comments, we considered incorporating these API and EI/JIG standards by reference, or drafting and including appropriate portions of these standards into part 1090. However, in reviewing the regulations we realized that the new provision proposed at 40 CFR 1090.615(e) may be superfluous with the existing requirement for product segregation throughout the entire distribution system now under 40 CFR 1090.615(c). The intent of proposed 40 CFR 1090.615(e) had been to enhance the prevention of product contamination in cases when both exempt and non-exempt fuels are being transported in the same transportation vessel. However, in some cases, this provision could have been interpreted as relaxing product segregation requirements when exempt fuels are being transported using transportation vessels totally dedicated to that fuel. This was not our intent. For this reason, we will continue to rely on the existing regulatory language at 40 CFR 1090.615(c).

Finally, California gasoline and diesel fuel used in California 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 sunsetted 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 creating provisions that clarify how California gasoline and diesel fuels may be used in states other than California. Under part 80, fuel manufacturers that make California gasoline and diesel fuel must recertify those fuels in order to sell them outside the state of California.[69] Under part 1090, we are providing California fuel manufacturers and distributors the choice of whether to recertify the California fuel, as currently required under part 80, or redesignate the California fuel without recertification if certain conditions are met. In order for a fuel manufacturer or distributor of California gasoline to redesignate without recertification such fuel for use outside of California, the fuel must meet all applicable requirements for California reformulated gasoline under Title 13 of the California Code of Regulations and the manufacturer or distributor must meet applicable designation and recordkeeping requirements.[70] Under part 1090, parties that redesignate California gasoline without recertification 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.[71]

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, PTDs, and gasoline

[68] API Recommended Practice 1595 and Energy Institute & Joint Inspection Group (EI/JIG) Standard 1530.

[69] Under part 80, fuel manufacturers of California gasoline that recertify their fuels must recertify their gasoline and comply with federal fuel quality standards (per-gallon and average standards).

[70] The explanation for the analysis we performed to determine the equivalency of the California fuel standards can be found in the technical memorandum, ''California Fuel Equivalency,'' available in the docket for this action.

[71] The California reformulated gasoline and diesel fuel standards are at least as stringent as the standards under part 1090; therefore, these fuels should be allowed to be used throughout the rest of the U.S. Cal. Code Regs. tit. 13, §§ 2281–2282 (2019).

segregation for fuels designated for export that currently apply under part 80 to part 1090.

In the NPRM, we proposed that in order for a fuel, fuel additive, or regulated blendstock to receive an export exemption, it would have to be segregated from the point of production to the point of exportation from the U.S. Commenters suggested that the inclusion of fuel additives and regulated blendstocks in the segregation requirement for exports was unnecessary, as exported fuel additives and regulated blendstocks do not need to be segregated and are unlikely to cause fuel quality issues if commingled. As such, we are not finalizing a segregation requirement for exported fuel additives and regulated blendstocks.

Regarding exported fuels, commenters suggested that we should only require that exempt fuels for export be segregated from non-exempt fuels from the point that the fuel was designated as for export until the fuel is exported. Commenters stated that the proposed segregation requirement could create challenges, as often times fuels for export are produced simultaneously with fuels for domestic use. To avoid unintended increases in the burden of producing domestic and exported fuels, we have revised the segregation requirement for fuels to begin at the point of designation.

Commenters also asked for more clarity on how diesel fuel export segregation requirements would work under part 1090. Under part 80, diesel fuel not designated for export can be exported without restriction as long as it meets the applicable fuel quality standards. However, the fuel remains subject to the provisions of this part while in the U.S. For example, diesel 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 designation until it is exported, as currently required under part 80.

We address other comments related to exports in Section 9 of the RTC document.

C. Extreme, Unusual, and Unforeseen Hardships

Under part 80, the various subparts associated with each standard include separate provisions for receiving an exemption from that subpart's fuel quality standards due to extreme, unusual, and unforeseeable hardship. We are consolidating these exemptions into one hardship provision for extreme, unusual, and unforeseeable circumstances (*e.g.,* a natural disaster or refinery fire excluding financial and supply chain hardship) that a refinery cannot avoid with prudent planning.[72] The part 1090 organization 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 applies only to the standards in part 1090; the parallel provision for the RFS program requirements remains in part 80. Accordingly, any exemptions available under the RFS program would similarly remain unaffected.

Commenters on the proposed extreme, unusual, and unforeseen hardship provision objecting to the explicit exclusion of financial and supplier difficulties from the grounds for hardship relief. The commenter described this language as a change from the extreme, unusual, and unforeseen hardship provisions of part 80. We believe that this is a clarification of the kinds of extreme, unusual, and unforeseen events that qualify for relief under this hardship provision under part 80. As such, we are finalizing the extreme, unusual, and unforeseen hardship provision as proposed and have addressed the comment in Section 9 of the RTC document.

VII. Averaging, Banking, and Trading Provisions

A. Overview

We have often used averaging, banking, and trading (ABT) provisions 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. As such, they are integral to our standards and we are transferring the currently applicable ABT provisions for gasoline sulfur and benzene from part 80 to part 1090.[73] In doing so, we are making modifications that will facilitate consolidation of these various ABT regulatory provisions in part 80 into a single set of ABT provisions in part 1090. In particular, this includes changes to how gasoline manufacturers can account for oxygenate added to gasoline downstream of fuel manufacturing facilities in compliance calculations. It also includes a new mechanism that allows downstream parties that recertify batches of gasoline to use different types and amounts of oxygenate downstream of a manufacturing facility. We are not transferring expired part 80 ABT provisions that were temporary provisions associated with initial implementation of the standards, such as the separate ABT provisions for small refiners and small volume refineries that expired at the end of 2019.

B. Compliance on Average

We are finalizing minor changes to the format of the average compliance calculations to align the sulfur and benzene compliance calculations more closely with each other and 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. These changes to the compliance calculations will not affect how gasoline manufacturers currently comply with the average standards or their stringency; however, the streamlined equations appear slightly different compared to the similar equations in part 80. We are also adding to the compliance calculation the deficits incurred on an annual basis due to the recertification of BOBs downstream to use a different type(s) and amount(s) of oxygenate. We discuss this change in detail in Section VII.G.

As previously noted, part 80 regulations had separate ABT provisions for small refiners and small volume refineries associated with the initial implementation of the gasoline sulfur and benzene standards that have expired. The last such provisions related to the Tier 3 gasoline sulfur program, which expired on December 31, 2019, resulting in small refiners and small volume refineries being required to comply with the same part 80 fuel quality standards and use the same ABT

[72] The part 80 programs generally had two hardship provisions: (1) Unusual circumstances that significantly affected the refiner's ability to initially comply by the applicable date, under which EPA allowed financial and supplier difficulties as a reason for additional lead time; and (2) extreme, unusual, and unforeseen events, like a natural disaster or refinery fire, that occur after the standards have become effective, and for which economic and supplier difficulties have never been a qualifying hardship event. Since part 1090 is not introducing new standards, we did not propose and have effectively removed the first (sunsetted) hardship provision, which allowed for financial and supplier difficulties for initial compliance relief, and are only keeping the second (ongoing) extreme, unusual, and unforeseen hardship provision.

[73] We do not have ABT provisions for diesel fuel, so this section is only applicable to gasoline.

provisions as other refiners. As a result, part 1090 does not include separate ABT provisions for small refiners and small volume refineries.

C. Deficit Carryforward

Under part 80 we allow gasoline manufacturers to carryforward deficits for the gasoline and sulfur benzene standards, 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. In part 1090, we are consolidating the separate gasoline sulfur and benzene deficit carryforward provisions from part 80 into a single provision and slightly modifying the language simply to accommodate the consolidation. We do not believe that the modifications will substantively affect how gasoline manufacturers are permitted to carry forward deficits.

Commenters requested additional flexibilities related to the deficit carryforward provisions. However, we are not finalizing any additional flexibility related to deficit carryforward. These comments are addressed in Section 10 of the RTC document.

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 making minor changes to the language largely to ensure consistency between the sulfur and benzene credit trading programs.

We are not making any changes to the lifespan of generated credits (*i.e.,* credits generated under part 1090 have the same lifespan as afforded them under part 80). Additionally, credits generated under part 80 are still 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 are still valid for compliance under part 1090 for the specified life of the credits under part 80. For example, credits generated for the 2020 compliance period could be used through the 2025 compliance period.

In general, we are finalizing the credit generation, use, and transfer provisions of part 1090 as proposed. We did, however, receive several comments that suggested clarifying edits to the regulations. These comments are addressed in Section 10 of the RTC document.

E. Invalid Credits

We are transferring the part 80 provisions for treatment of invalid credits to part 1090 without modification. Since the establishment of the sulfur and benzene ABT programs, we migrated tracking of credit transactions into the EPA Moderated Transaction System (EMTS). We did not receive substantive adverse comments related to the treatment of invalid credits under part 1090 and we are finalizing the provisions related to invalid credits under part 1090 as proposed. We did however receive a comment asking about published guidance for remedial actions to address issues related to invalid credits in EPA electronic reporting systems. We address this comment in Section 10 of the RTC document.

F. Downstream Oxygenate Accounting

Under part 80, we 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, test the hand blend for reported parameters, and include these values in their compliance calculations to demonstrate compliance with the sulfur and benzene average standards and the RFG performance standards. The refiner or importer then specifies the type(s) and amount(s) of oxygenate 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.

While there are provisions in part 80 for refiners and importers of CG to also account for downstream oxygenate addition, they are much more limited and difficult to utilize given the fungible nature of most CG and conventional gasoline before oxygenate blending (CBOB) and the requirements imposed. 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/CBOB. This regulatory disparate treatment of CG and CBOB compared to RFG and reformulated gasoline before oxygenate blending (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 at a time when virtually all gasoline now has ethanol added downstream.

In order to remedy this disparity, we are finalizing a single method for gasoline manufacturers to account for oxygenate added downstream of a fuel manufacturing facility to comply with the average sulfur and benzene standards, as proposed. In part 1090, we are requiring gasoline manufacturers to use ''hand blends'' when accounting for oxygenate added downstream. We are also requiring that oxygenate blenders follow instructions for the type(s) and amount(s) of oxygenate from the BOB manufacturer. These requirements for gasoline manufacturers and oxygenate blenders under part 1090 largely mirror the requirements for oxygenate blending and accounting found in the RFG program under part 80.

The main differences between the part 1090 hand blend approach and the part 80 RFG program is that the accompanying in-use survey under part 1090 will be national in scope (instead of just a survey of RFG areas), and the BOB manufacturer must participate in NSTOP.[74] Additionally, since we are broadening the scope of the oxygenate accounting process from RBOB to all BOB, we are also requiring that gasoline manufacturers prepare samples using the hand blend procedures in ASTM D7717 and that commercially available oxygenate (*e.g.,* DFE) 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 part 1090 requirements are the same as currently specified for the RFG program under part 80.

In the NPRM, we sought comment on whether to allow for alternative mechanisms for downstream oxygenate accounting. We received comments suggesting that we include provisions to allow fuel manufacturers to use a set of specified assumptions for benzene, sulfur, and oxygenate content values to account for oxygenate added downstream. For reasons discussed in detail in Section 10 of the RTC document, we are only finalizing the proposed hand blend approach.

We also received other comments with suggestions or requests for clarification regarding the downstream oxygenate accounting provisions, which we have reflected in the final regulations as appropriate. We address these comments in Section 10 of the RTC document.

[74] The accompanying in-use survey requirements and the NSTOP are discussed in more detail in Section X.

G. Downstream BOB Recertification

We are finalizing provisions that will allow parties to recertify BOBs downstream for different type(s) and amount(s) of oxygenate (including E0) if certain requirements are met. Under the part 80 RFG program, oxygenate blenders must add the type(s) and amount(s) of oxygenate to RBOB as specified by refiners.[75] 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 the cost associated with recertifying batches of RBOB downstream in keeping with these requirements under the part 80 RFG program, oxygenate blenders have not typically opted to assume the role of a gasoline refiner. This has all but precluded the availability of E0, E15, and the use of isobutanol in RFG areas. The batch sizes are relatively small (typically the volume of a single tanker truck) and do not support the added cost.

These restrictions, currently limited to RFG areas under part 80, would have been compounded by the expansion of the downstream oxygenate accounting flexibility to all gasoline under part 1090 discussed in Section VII.F. As such, we are including 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.

Under part 1090, we are requiring 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, they would need to make up for the lost dilution of the sulfur and benzene in the national gasoline 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 use default assumed values for the amount of sulfur and benzene from the BOB and are setting default values of 11 ppm sulfur and 0.68 volume percent benzene. These values are reflective of the national sulfur and benzene average values adjusted for the absence of DFE added at 10 volume percent ethanol.[76] The goal of these 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 will be low and small changes from actual benzene and sulfur content will likely be offset by improved compliance oversight in other areas of the program, as discussed in Section XIV.

We received comments on the proposed compliance calculations for downstream BOB recertification and have made some minor modifications based on suggestions from commenters. These changes are discussed in more detail in Section 10 of the RTC document.

In cases where a party adds the same volume of oxygenate or more, these credit makeup regulations do not apply, as more than enough sulfur and benzene dilution will have occurred (*e.g.,* 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 EPA regulations 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) or meet all waiver conditions under CAA section 211(f)(4). 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 does 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.

We received several comments asking for clarity on how the downstream BOB recertification requirements apply to parties that add the same or more oxygenate to a BOB. We have added language to the regulations that clarify that these parties do not incur deficits and are not expected to submit additional reports as fuel manufacturers. We address these comments in Section 10 of the RTC document.

In order to ensure that parties that recertify BOBs downstream adhere to the provisions for downstream oxygenate recertification, we are requiring that these parties register with EPA, transact for 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 requiring that these parties simply undergo an annual attest engagement audit and submit an attest report similar to the report required for gasoline manufacturers. These 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, they must include the total number of credits needed as a result of downstream oxygenate recertification in their annual compliance calculations as a deficit.

In the NPRM, we proposed to exempt parties that blended 200,000 gallons or less per year from the annual attestation audit for purposes of reducing the potential costs for small volume blenders that recertify BOBs. We sought comment on both the 200,000-gallon threshold and whether additional flexibility was needed to control costs for small volume blenders. Several commenters requested an increase of the annual threshold, ranging from 1,000,000 to 2,000,000 gallons per year. We also received several comments suggesting that we exempt these small volume blenders from not only the annual attestation engagement, but also the deficits themselves or from having any compliance burden whatsoever. Commenters argued that without either increasing the threshold or reducing the compliance burden, BOB recertification would still be prohibitively expensive and limit the availability of E0 and isobutanol blends for vehicles and engines where their use is recommended (*e.g.,* marine engines).

[75] See 40 CFR 80.69.

[76] We took the national average values for sulfur (10 ppm) and benzene (0.62 volume percent) and multiplied them by 110 percent.

Based on these comments, we believe it is appropriate to both increase the exemption threshold and provide additional flexibility for small volume blenders to avoid unnecessarily increasing the costs of such blends. Therefore, we are increasing the annual threshold to 1,000,000 gallons per year. We are also exempting parties that blend 1,000,000 gallons or less per year from incurring sulfur and benzene deficits related to downstream BOB recertification. In combination, we believe these changes will provide adequate flexibility for parties that recertify BOBs to supply E0 and isobutanol blends while also ensuring that large volume blenders do not significantly increase the national average sulfur and benzene levels. These small volume blenders are still required to register, report, and keep records under part 1090. We believe these requirements are necessary to help ensure oversight of the program and do not anticipate that this will substantially increase burdens on such blenders, as many of these parties already are registered with EPA and submit reports under part 80.

Because the downstream BOB recertifications were a new flexibility under part 1090, we sought comment on several issues, including whether there were alternative mechanisms to allow for downstream BOB recertification that would be less burdensome. While several commenters suggested that the proposed downstream BOB recertification provisions were unnecessary, we did not receive any comments suggesting an alternative mechanism to allow parties to recertify BOBs downstream. We address comments suggesting that the downstream BOB recertification provisions are unnecessary in Section 13 of the RTC document.

We did not propose a deficit carryforward for deficits incurred from downstream BOB recertification, as we believed that the amount of credits needed to satisfy such deficits would be relatively small, parties may fail to satisfy those deficits, and enforcement would be impractical. Nevertheless, we sought comment on whether to allow for a deficit carryforward for deficits incurred under the proposed downstream BOB recertification provisions. Several commenters suggested that we should provide such deficit carryforward provisions. However, in light of the exemption provided for volumes up to 1,000,000 gallons per year as discussed earlier, and for reasons explained in more detail in Section 13 of the RTC document, we are not providing deficit carryforward provisions for deficits incurred from downstream BOB recertification.

Several other commenters suggested modifications to the downstream BOB recertification provisions. We address these comments in Section 13 of the RTC document.

VIII. Registration, Reporting, Product Transfer Document, and Recordkeeping Requirements

A. Overview

This rule transfers and consolidates many of the existing part 80 registration, reporting, PTD, and recordkeeping provisions in new part 1090. As discussed in the NPRM, we have sought to reduce the impacts on regulated parties and reduce the burden associated with maintaining and submitting information, an approach generally supported by commenters. In certain cases, we have simplified and better aligned reporting requirements with current industry practice, which is particularly true of the batch reporting requirements described in greater detail in Section VIII.C.

Except for certain information discussed in Section XIII.H, 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 treat such information from public release in accordance with the provisions of 40 CFR part 2, subpart B. 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. Information that may be publicly released 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. We did not propose a comprehensive CBI determination and, therefore, are not finalizing one here.

B. Registration

1. Purpose of Registration

Registration is necessary to: (1) Identify parties engaged in regulated activities under EPA regulations; (2) allow regulated parties access to systems to submit information required under EPA's fuel quality regulations; and (3) provide regulated parties with company and compliance-level identification numbers for producing PTDs and other records. Part 1090 makes modest changes to the existing registration system, including modernizing certain terminology and updates that make registration easier to understand and implement.

A number of commenters sought clarification on the proposed registration requirements under part 1090 and we have incorporated them to the extent appropriate. We address these comments in detail in Section 11 of the RTC document.

2. Who Must Register

The registration regulations update terminology to better reflect current roles and activities in the fuel production and distribution system. This rule includes registration requirements for certain third parties, such as auditors. These are explained in greater detail below. The following parties must register 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 under 40 CFR 1090.515(g)
- 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 are subject to registration under part 1090 are already registered under part 80. We did not propose to require parties who are already registered under part 80 to go through the effort to re-register their company or their facilities under part 1090. Some commenters specifically stated that they believe parties should not have to re-register and we agree.

Part 1090 includes specific provisions that 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'' are covered under this new term and do not have to re-register. We do not believe that migration of part 80 requirements to part 1090 will result in a significant number of new registrants, and existing registrants will 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). Existing registrants may also need to access the registration system in order to associate with auditors or other third parties who will submit reports on their behalf. Association is a step within the existing registration system and is designed to ensure that the company for which the reports are submitted by a third party 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.

Part 1090 removes the registration requirement for independent laboratories that existed in part 80. As a result, independent laboratories are no longer required to register unless they submit information directly on behalf of another party, such as a gasoline manufacturer. In such cases, they will need to update their registration to reflect that they are submitting reports on behalf of a regulated party and will have to associate with the company or companies for which they will submit reports.

We are finalizing registration requirements for independent surveyors and auditors under part 1090. These parties were 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. Independent surveyors perform the compliance surveys and the 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.9, independent surveyors have to register with EPA 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. Having the independent surveyor register and be able to submit reports via EPA's established reporting system will allow us to more quickly publicly post in-use survey results.

As also previously noted, auditors already performed 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 engage an auditor to perform the attest engagement, and the auditor gives the attest engagement to the party who then must submit it to EPA. Some parties have found this process cumbersome. In order to streamline the reporting process, we proposed to establish a means by which auditors may submit the attest engagement directly to EPA and in a manner that ensures the party for whom it was performed is aware of the submission. To implement this change, auditors will register and associate with the regulated party; then, the auditor will submit reports directly to EPA. This will ensure that they are submitting reports on behalf of a regulated party and that the attest engagement is properly submitted. This will also help EPA to contact the company and the auditor regarding any difficulty with the submission.

3. What Is Included in Registration

Like the existing provisions in part 80, registration under part 1090 entails 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 set up the necessary accounts. Part 1090 updates the terminology for companies to more modern usage; it does not change the fundamental activity or purpose of registration.

4. Deadlines for Registration

Under part 80 new registrants have to register 60 days prior to engaging in regulated activity. This timeframe remains a useful guideline, as we must be allowed an appropriate amount of time to process and activate registration-related requests. Part 1090 requires that registration occur 60 days prior to a party engaging in any activity that requires registration. We are retaining the requirements from part 80 that updates to existing registration must occur within 30 days of the event requiring the change. As previously discussed, we do not expect many new registrants under part 1090, as existing registrants under part 80 will continue to be registered under part 1090. Company and compliance-level (*e.g.,* facility) identification numbers issued under part 80 will remain valid under part 1090. We do, however, anticipate newly registering up to 100 auditors, one surveyor, and 50 third parties.

5. Changes in Ownership

As explained in the NPRM, we have received feedback over the years from registrants that changes in ownership should be addressed more clearly in the regulations. Consequently, we proposed provisions to clarify how a company may initiate a change in ownership for registration purposes. The provisions on updating registrations for ownership change largely codify existing guidance provided to companies under part 80.

Part 1090 clarifies that companies will 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. In the case of a change in ownership requiring an update to an existing registration, a company will 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 will 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 as currently required under part 80) is not workable due to how ownership changes are effectuated in the business world. Although we did not propose, and are not finalizing, a specific, advance deadline, we note that it may take several days or weeks 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 to ownership change as a good guideline. Based on our experience with ownership changes under part 80, companies will 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 complicated and involve many facilities, 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 finalizing 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 of which 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. Cancellation of Registration

We are finalizing new provisions for voluntary and involuntary cancellation of registration under part 1090. 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 under part 1090.

Voluntary cancellation is initiated by the registered party (*e.g.,* if the party's business changes and it no longer engages in an activity that requires registration). We are including voluntary cancellation language in part 1090 because registered parties often ask for clarification of the procedure involved.

Involuntary cancellation is 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 will provide notification of our intention to cancel the party's registration and the registrant will 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 30 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. Several commenters noted that there was a discrepancy in the NPRM between the preamble and the regulations regarding the period by which missing reports must be received. The NPRM preamble said 14 days, but the regulatory text said 30 days. We are clarifying that we intended the longer response time (*i.e.,* 30 days).

In instances of willfulness or where public health, interest, or safety requires, EPA may deactivate the registration of the party without any notice to the party. In such cases, EPA will provide written notification to the RCO identifying the reason(s) EPA deactivated the registration of the party. We expect such situations to be extremely rare.

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 reducing the number of parameters to be tested and reported and, in some cases, reducing the required frequency of reporting.

A number of commenters sought clarification on the proposed reporting requirements under part 1090 and we have incorporated them to the extent appropriate. We address these comments in detail in Section 12 of the RTC document.

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 in Section VIII.B, certain parties are required to register to receive company and compliance-level identification numbers for use on PTDs and for recordkeeping, although they do not have reporting requirements under part 1090. For example, parties involved in the manufacture and distribution of 500 ppm LM diesel fuel are required to register and receive company and compliance-level identification numbers to use on PTDs and records but do not submit reports under part 1090.

3. Key Differences Between Part 1090 and Part 80

We are eliminating 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 (as a percent reduction from baseline)
- VOCs (as a percent reduction from baseline)
- Exhaust Toxics Emission
- Other identifying information (*i.e.,* Batch Grade, lab waiver, independent lab analysis requirement)

We are retaining the four main parameters for gasoline reporting: Sulfur, benzene, RVP, and oxygenate type/content.[77] The parameters being eliminated from reporting, although once useful, are no longer needed in reports, as discussed in Section V.A.2. Removing these parameters reduces compliance costs related to reporting, sampling, and testing, without sacrificing our goal of protecting human health and the environment. Under part 1090, we are also simplifying the annual, batch, and credit transactions reporting, which results in many fewer forms and data elements for respondents.

Under part 80, there are numerous reporting forms in use; these reporting forms are now simplified and reduced under part 1090. Reporting forms and format 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. 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. In doing this, we are also eliminating collection of information that is no longer necessary, reducing the number of parameters and test methods reported, simplifying the type and number of reports to be filed, and, in many cases, reducing the frequency of reporting (*e.g.,* going from quarterly to annual).

The reporting requirements for gasoline manufacturers include 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.
- 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.
- 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 regulations address reporting for gasoline, oxygenates, and regulated blendstocks and explain 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 detailed color-coded batch reporting summary table as part of the reporting form instructions and this table reflects 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.
- Attest engagements. Under part 1090, we have changed the method of submission of annual attest engagements. Under part 80, refiners and importers submit attest engagement reports themselves. Under part 1090, the attest engagement report will be submitted on the fuel manufacturer's behalf by the auditor. Fuel manufacturers remain responsible for engaging an auditor to conduct the attest engagement, and for ensuring that a proper attest engagement is submitted to EPA. To do this, as explained in Section X.A.2.d, the auditor will register with EPA and be associated with a registered company. To ensure that the auditor and the company for whom they are preparing the report agree, these parties must associate with each other within the registration system. This action aligns the submission of the attest engagements under part 1090 with the requirements of the RFS program. We had proposed that the attest engagement submission would require a description of the findings and the steps the regulated party would take to address remedial actions, but did not require that all the remedial action steps occur before submission. We are finalizing the requirement that the submission include a description of the findings. We are not finalizing the requirement that the submission by the auditor address remedial actions related to the attest engagement, as we agree with commenters that this report item may be beyond the normal scope of the auditor. Some commenters expressed a desire to receive the attest engagement report prior to submission to EPA by the auditor; we believe that this is within the ability of the party to arrange with the auditor and need not be specified in the regulations. The auditor and the party with whom they are associated (and for whom the attest engagement was prepared) will be able to download the report submitted to EPA. Attest engagements are discussed in detail in Section XII.B.

5. Reporting Requirements for Gasoline Manufacturers That Recertify BOB for Different Type(s) and Amount(s) of Oxygenate

In order to implement the optional provisions discussed in Section VII.G with respect to treatment of BOBs, we are finalizing 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 BOB manufacturer, they will 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.[78] Credit transactions associated with re-certification of the BOB will also be reported. Parties that recertify BOBs may include all volumes and deficits in a single reported batch of up to 30 days. (Allowing this reduces the reporting burden.)

[77] For batches that are certified using the hand blend approach (discussed in more detail in Section VII.F), the hand blend will not typically be tested for oxygenates; however, gasoline manufacturers will report the type and amount of each oxygenate blended to make the hand blend. Manufacturers that certify batches of gasoline using a different approach will still need to test and report oxygenate content unless they can demonstrate that the gasoline contains no oxygenate (*i.e.,* the gasoline is E0). Furthermore, in all cases, we only require that gasoline manufacturers report the oxygenates added or tested for, instead of reporting information for all potential oxygenates. We believe this greatly simplifies oxygenate reporting requirements compared to part 80.

[78] 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.

6. Reporting for Oxygenate Producers and Importers

Similar to part 80, oxygenate producers and importers must submit batch reports providing information about the oxygenate they produce or import. Reporting for oxygenate producers is 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 DFE, the reported information will specify whether the denaturant is certified ethanol denaturant or non-certified.

7. Reporting for Certified Pentane Producers and Importers

Similar to part 80, certified pentane producers and importers must 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.

8. Reporting by Diesel Manufacturers

We are finalizing limited batch reporting for manufacturers of diesel fuel. Specifically, manufacturers of diesel fuel (excluding 500 LM diesel fuel from transmix) that test any batch found to exceed the applicable 15 ppm sulfur standard must report information about that batch. Batches that do not exceed the applicable 15 ppm sulfur standard will not be reported to EPA. The specific information 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, the burden of reporting a relatively small number of batches found to exceed the applicable 15 ppm is small. This limited batch reporting will assist us in our compliance oversight efforts and in ensuring that the human health and environmental benefits of the program are realized. This action also transitions the diesel fuel property reporting from part 79 to part 1090 in a simplified form, which 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).[79] We believe that the simplified property reporting for diesel fuel will help us better oversee the fuel quality requirements or diesel fuel under part 79 and part 1090.

9. Reporting by Independent Surveyors

Independent surveyors are required to register and report. The 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 are also expected to comply with an annual reporting requirement that addresses summary statistics and describes compliance rates and non-compliance issues. Independent surveyors must also submit similar reports under NSTOP. The independent survey program and NSTOP are discussed in Section X.

10. Deadlines for Reporting

The following reporting deadlines apply to part 1090:

- Annual compliance reports for sulfur and benzene 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 March 31, 2022).
- Batch reports must be submitted by March 31 for the preceding compliance period.
- Attest engagements must be submitted by auditors by June 1 for the preceding compliance period.
- Reports by independent surveyors will 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.

Part 1090 reporting deadlines are the same as part 80 with one exception. Under part 80, RFG refiners and importers had to submit quarterly batch reports compared to CG refiners and importers who only had to submit annual batch reports. Under part 1090, we are requiring that all batch reports must be submitted annually for all gasoline manufacturers.

Some commenters had suggested that aligning the compliance reporting and the attest engagement due date of June 1 might lead to fewer report resubmissions, and that the auditor would be able to perform the attest engagement using the batch reports that were due on March 31. Although we agree that reducing resubmissions of reports is a consideration, we must balance this against the compliance need to be able to process and utilize ABT and credit reports in a timely manner and against the data transparency purpose of making information about the program available to the public in a timely manner. Therefore, we are finalizing the reporting deadlines as proposed.

11. Reporting Forms

We have docketed the reporting forms and have submitted them to OMB for review with the ICR for this rule. We received several comments related to the content and structure of the forms and have amended several forms in response to these comments. We address these comments in detail in Section 12 of the RTC document.

D. Product Transfer Documents (PTDs)

The general purpose and requirements for PTDs under part 1090 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. 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 removes PTD language that is no longer needed and provides standard, updated language to address a variety of common products and situations. We are, however, making some minor modifications from the part 80 requirements.

The PTD requirements apply on each occasion when any person transfers custody or title of IMO marine fuel except when the IMO marine fuel is dispensed for use in marine vessels. Part 1090 incorporates the Bunker Delivery Note (BDN) requirements from 40 CFR 1043.80 to address the transfer of IMO marine fuel by a fuel supplier onto a vessel.[80] Each fuel supplier is independently responsible for meeting the BDN requirements. However, the BDN requirements must be met only once for each delivery of fuel onto a vessel. As a result, if the BDN requirements are properly met by the fuel supplier that transfers custody or the fuels supplier who transfers title of the fuel onto a vessel, EPA will consider the requirements to have been met by each fuel supplier. This approach

[79] Diesel fuel manufacturers must still submit periodic reports related to the additives used in their diesel fuel as specified under 40 CFR 79(a)(1).

[80] A fuel supplier includes a person who transfers custody or title of marine fuel to a vessel.

provides parties with the flexibility to contractually allocate the BDN responsibilities as they see fit among themselves and ensures that the BDN requirements will be met. Pursuant to 40 CFR 1043.80, each fuel supplier must keep copies of the BDNs.

As proposed, we are including 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 in its language requirements across the various part 80 fuel quality programs. To make our PTD requirements more consistent, we are requiring 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 requirements. To address these potential issues, we are adding flexibilities for parties to seek approval for alternative PTD language for all PTD language requirements. Based on experience implementing part 80, we do not anticipate that many parties will request alternative PTD language.

We received several comments suggesting clarifying edits to the PTD requirements to help the part 1090 regulations address common situations that arise in the production and distribution of fuels. We address these comments in Section 13 of the RTC document and have reflected these suggestions where appropriate in the part 1090 regulations.

E. Recordkeeping

Part 1090 contains the same record retention requirements as those in part 80. All parties that were required to keep records under part 80 will 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 will decrease.

In general, we received few comments on the proposed recordkeeping requirements. These comments suggested edits to the regulations for clarity. We made slight modifications to the regulations in response to these comments. These comments are addressed in Section 14 of the RTC document.

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 calculations of 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. As proposed, we are finalizing a much broader and consistent approach in part 1090 using the standard approach to rounding in 40 CFR 1065.20 that is consistent with ASTM E29. We are requiring this rounding protocol for all recorded values under part 1090.

Part 1090 includes additional specifications for calculating and recording numerical values. First, we are specifying 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 requiring 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 does not 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.

We did not receive any comments on the rounding provisions and we are finalizing the rounding provisions as proposed with one exception. In order to avoid confusion associated with the rounding of batch volumes for small batches of fuel that might be produced in standard-size tanker truck volumes, we are changing the batch size threshold for rounding to the nearest 10 gallons from 10,000 to 11,000 gallons.

G. Certification and Designation of Batches

We are finalizing the batch certification and designation provisions largely as proposed. 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 currently outlined in guidance. We are incorporating such guidance into part 1090 and establishing a clear process to certify batches. The

part 1090 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 certify products under part 80. These requirements also satisfy CAA section 211(k)(4) describing certification procedures for RFG.

Regarding designation, for gasoline and gasoline-related additives and regulated blendstocks, we are modifying the designation requirements for these products. Most of these 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 removing those designations. Additionally, we are providing flexible redesignation provisions for distributors of gasoline. These proposed provisions largely reflect the streamlining of the RFG program and the more fungible nature that results.

Under part 1090, distributors of gasoline are 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 resultant mixture and designate the new batch accurately to reflect the RVP of the gasoline as described under this section. When transitioning tanks from winter to summer gasoline, parties are not required to test the RVP but must be able to assure that the gasoline meets the applicable RVP standard.

We are also making it clear in part 1090 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 maintaining the part 80 designation requirements. We are, however, making two notable changes. First, we are providing for a more flexible ULSD designation for distillate fuels certified to meet ULSD standards. The intent of this flexibility is to ensure that fuels that meet the ULSD standards could be designated as necessary to be used as home heating oil, MVNLRM diesel fuel, or IMO marine fuel. This change will allow parties to make sure that fuels are designated appropriately throughout the distribution system.[81] Second, similarly to gasoline, we are allowing parties to redesignate California diesel fuel that meets the ULSD standards without recertification. We believe the designation changes for diesel fuel would help maximize the fungibility of distillate fuels that meet the ULSD standards.

We received several suggestions and requests for clarification regarding the certification and designation provisions under part 1090 from commenters and have made slight modifications to the regulations in response to these comments. We address these comments in Section 13 of the RTC document.

IX. Sampling, Testing, and Retention Requirements

Our fuel quality programs consist 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 test procedures essentially unchanged from part 80 into part 1090 and updating them in the process as proposed. We are also reorganizing the testing provisions in part 1090 and codifying 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 changes relative to what currently applies under part 80.[82]

A. Overview and Scope of Testing

Part 80 requires gasoline manufacturers to measure 11 complex model parameters. As proposed, and in keeping with the discussion in Section V.A.2, for part 1090 we have reduced this to just three parameters: Sulfur, benzene, and RVP (in summer) for all gasoline, except for some unique situations discussed in more detail below. Diesel fuel manufacturers will continue to have to test for the sulfur content.

Similar to part 80, under part 1090, gasoline manufacturers will also be required to sample and test finished fuels for oxygenates unless the gasoline manufacturer is making gasoline without oxygenates. 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. This will provide some confirmation that the blended product has a distillation profile that is generally consistent with gasoline meeting the substantially-similar requirements of the CAA. The results of the distillation testing is not 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 gasoline manufacturers.

Under part 1090, CG refiners and diesel fuel manufacturers must 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. 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 refinery.

Similar to part 80, we are requiring under part 1090 that all gasoline manufacturers obtain test results for sulfur and RVP (during the summer months) before shipping gasoline from the fuel manufacturing facility. Part 80 also requires refiners to obtain test results for benzene before shipping RFG, but does not require refiners to first obtain these results for CG. Under part 1090, we are not requiring gasoline manufacturers to test for benzene before shipping gasoline from the fuel manufacturing facility.

We are maintaining part 80 exceptions to testing under current waivers that do not require measurement of fuel properties prior to

[81] This action does not address how these fuels are accounted for inclusion in obligated parties' renewable volume obligation (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 7054–57, February 6, 2020).

[82] 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.

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 proposed to allow for the in-line blending waiver only for certain shipment configurations that do not allow for conventional batch testing. We received comments requesting that we clarify whether storage tanks prior to pipeline injection, typically used to accommodate cases where gasoline needs to be held prior to pipeline injection, could be included in an in-line blending waiver request. Under part 80, we have allowed such storage tanks to serve as an extension to the pipeline system as these tanks are typically not suitable for use as a certification tank. Based on these comments, we have revised the final rule to continue allowing the approach from part 80 in which refiners may apply for the in-line blending waiver for shipment configurations that include storage tanks that act as an extension of the pipeline system.

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 part 80 sampling procedures and demonstration of homogeneity of fuel samples that are currently specified in 40 CFR 80.8 to part 1090 as proposed. 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 relating 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.[83] We are reflecting that guidance in part 1090 by adding numerous minor clarifications and adjustments to the regulatory text to reflect current best sampling practices. Several commenters suggested edits to the proposed regulations, as well as sought clarification of the various sampling procedures for fuels. We have reflected these comments in the final regulations as appropriate, and address these comments in Section 15 of the RTC document.

2. Sample Preparation for BOB Testing

Section VII.F describes the ''hand blend'' approach for gasoline that would allow gasoline manufacturers to account for the impacts of downstream blending of oxygenate into BOB in their sulfur and benzene compliance calculations.[84] The hand blend procedure involves 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, as a result of homogeneity testing, three tested BOB samples are commonly 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 addressing these examples of discretion in the specified procedures by requiring that the hand blend represent a worst-case test condition with respect to oxygenate content. In the case of sulfur measurements from multiple samples to represent a batch of BOB, the regulation requires taking steps to avoid introducing high or low bias in sulfur content when selecting from available samples to create the hand blend.

Under part 1090, winter gasoline must 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 approach is necessary to properly select the type and amount of oxygenate for hand blending in summer gasoline to properly account for the impacts on RVP. Summer gasoline will need to be blended with the lowest specified percentage of oxygenate 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 part 80 regulations requires sample retention for 30 or 90 days. We are requiring 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 oil 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 leased terminal tanks). We therefore believe it is appropriate to require a longer retention period for blending manufacturers to help trace potential issues with fuel quality. We proposed 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. We received several comments suggesting that the proposed 120-day retention period was too long. Commenters contended that such a long retention period would result in the need to develop new capacity to retain fuel samples which would be quite burdensome. Commenters suggested a range of different retention periods from 30 days, as proposed for other fuel manufacturers, to 90 days. In response to these comments, we now believe that a 90-day retention window is the most appropriate balance to ensure robust controls on fuel quality from fuels made by a blending manufacturer. We address this issue in more detail in Section 15 of the RTC document.

For testing BOB and hand blended samples of oxygenated gasoline as described in Section IX.C, the sample-retention requirements apply for only for the BOB sample. 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

[83] 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.

[84] The regulations at 40 CFR 80.69 and 80.101 practically limits this practice to RBOB. As discussed in Section VII, we are making it more practical for all fuel manufacturers of BOB to account for the addition of oxygenate added downstream. Part 80 also does not currently specify preparation procedures for hand blends.

demonstrate compliance. For any testing, with the retained sample, EPA or the fuel manufacturer would use any standard supply of DFE or other oxygenate to re-create the hand blend.

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 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. As discussed in Section X.A.2, the independent surveyor will test for the full suite of Complex Model gasoline parameters, and testing will be performed by an EPA-approved test lab on fuels intended to represent the range of fuels in distribution over time.

Survey measurements must 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 received comments asking for minor clarification on the test procedures that independent surveyors would use under part 1090. We have reflected these comments on the final regulations as appropriate, and address these comments in Section 15 of the RTC document.

2. Procedures To Determine Cetane Index for Diesel Fuel

Part 80 and the CAA establishes a cetane index standard at or above 40 for diesel fuel used with motor vehicles and nonroad equipment.[85] 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. We proposed to allow the use of both ASTM D976 and ASTM D4737 in determining cetane index and received comments in support. As such, the final rule specifies that either of the referenced ASTM procedures are acceptable for determining cetane index for diesel fuel.

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 exempting biodiesel from testing to verify compliance with the cetane index or aromatic content requirement for diesel fuel.

Several commenters suggested that we should modify our proposed definition for biodiesel to tie it to industry specifications under ASTM D6751. These comments noted that the proposed definition only required that biodiesel contain a minimum 80 volume percent mono-alkyl esters and asked EPA to clarify what the other 20 volume percent of the biodiesel could be.

While we do not believe that we should limit biodiesel covered under part 1090 to only biodiesel that meets ASTM D6751 (this issue is addressed in more detail in Section 4 of the RTC document), we appreciate the need for clarification regarding which biodiesel fuels are exempt from cetane index/aromatics testing. We believe, based on suggestions from commenters, that exempting all biodiesel from cetane index and aromatics testing, while allowing biodiesel to contain 20 volume percent of substances other than mono-alkyl esters, would not be appropriate. We also believe that ASTM D6751 provides sufficient limitations on the concentrations of impurities in biodiesel to ensure that the biodiesel would not have any aromatics content, thereby meeting the cetane index/aromatics diesel fuel requirements. Therefore, we are finalizing that biodiesel that meets ASTM D6751 is exempt from cetane index and aromatics testing under part 1090. Conversely, biodiesel or biodiesel blends that do not meet ASTM D6751 are not exempt from cetane index and aromatics testing.

3. Performance-Based Measurement System

Part 80 contains the Performance-Based Measurement System (PBMS) that establishes objective criteria for qualifying laboratories and measurement procedures.[86] 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 broadening 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 quality audits such as what is required for in-line blending waivers, for truck and rail imports where the importer has elected to comply with the alternative per-gallon standards, and for blending certified butane and pentane into PCG. Any other application 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 to part 1090 that currently apply under part 80, subject to the following exceptions and clarifications.

First, we are changing the designated referee procedure for measuring benzene in gasoline from ASTM D3606 to ASTM D5769. We believe ASTM D5769 is 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 and the prevalence of ethanol in gasoline now makes its use more challenging. Since ASTM D3606 is

[85] See CAA section 211(i) and 40 CFR 80.520(a)(2).

[86] See 40 CFR 80.46 and 80.47.

the referee procedure for measuring benzene in gasoline under part 80, we are waiving 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. We received several comments suggesting that we should not update the referee procedures for benzene from ASTM D3606 to ASTM D5769. These commenters mostly highlighted potential logistical issues with converting to a new designated referee method but not with the method itself. As such, we continue to believe that ASTM D5769 should be the referee method, as it does not suffer from matrix effects when testing gasoline-oxygenate blended fuels, which are predominant in the marketplace today. We address this issue in more detail in Section 15 of the RTC document.

Second, we are removing measurement of aromatic content in diesel fuel from the PBMS protocol since, consistent with part 80, we are not requiring aromatics testing for every batch of diesel fuel under part 1090. 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 specifying ASTM D1319 and ASTM D5186 as acceptable procedures for measuring aromatic content in diesel fuel and allowing for alternative procedures that correlate with either of these specified procedures.

We proposed to specify ASTM D6667 as the procedure for measuring sulfur in pentane. Based on comments, we have revised the final rule to instead specify ASTM D5453 as the appropriate method as discussed in Section 15 of the RTC document.

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 DFE, 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. We did not receive any comments on subjecting oxygenates to the PBMS requirements and are finalizing these provisions as proposed.

c. Updated Versions of Referenced Procedures

EPA fuel regulations rely on 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, part 1090 allows laboratories to use updated versions of referee procedures or qualified alternative procedures without prior approval from EPA, as long as the updated version has published repeatability and reproducibility that is the same as or better than the version referenced in part 1090.

Laboratories wanting to use an updated method of a referee procedure to qualify alternative procedures must first get EPA approval because using an updated referee method to qualify an alternative method could potentially change the baseline for which other previously approved alternative methods were compared. This could create disparities in how alternative methods are qualified, and we would like the ability to ensure that such disparities do not result in inappropriate qualification of new alternative methods. 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. 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 unchanged with two exceptions. First, we 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 specify precision and accuracy criteria for gasoline benzene based on the most recently published reproducibility values from ASTM D5769 instead of ASTM D3606 in keeping with the change in the designated referee method described in Section IX.C.3.b. 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 require 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 allows 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 is difficult for measuring sulfur in neat biodiesel, since it has inherently low sulfur concentrations. We 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.

Part 1090 requires the between-methods-repeatability, R_{xy}, for qualifying alternative procedures for method-defined parameters using non-VCSB methods to 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 as a viable option.

e. Ongoing Testing for Statistical Quality Control

Further, we are transferring the statistical quality control procedures (SQC) established under 40 CFR 80.47 to part 1090. By rewriting these procedures in their own section, the provisions in part 1090 will likely clarify some points that were previously subject to differing interpretations. We have also updated the SQC procedures to the latest version of ASTM D6299. This should provide additional flexibility to meet ongoing SQC requirements. We address other comments related to ongoing SQC requirements in Section 15 of the RTC document.

X. Third-Party Survey Provisions

Third-party verification plays an important role in overseeing compliance with EPA's fuel quality programs under part 80. One key element to the existing third-party oversight regime is in-use retail level surveys. An advantage of retail survey programs is that they target fuel quality at the point where 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 ethanol content, which are tracked in RFG areas, and 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 pool. We are finalizing provisions for a national survey program in part 1090 that will consolidate the four programs under part 80 into a single national in-use retail survey program, thereby reducing overall costs, while at the same time expanding the benefits of the survey program nationwide. The part 1090 survey builds upon the part 80 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,[87] and reducing the number of fuel parameters that fuel manufacturers need to test and report.

Part 1090 includes two survey programs: (1) A national survey program of retail outlets that offer gasoline and diesel to ensure that in-use standards are met; and (2) a voluntary national sampling and testing oversight program (NSTOP) 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 EPA's fuel quality program. This section discusses both programs in detail.

A. National Survey Program

As previously explained, we are finalizing 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 EPA's 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 relying 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). 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 part 80 compliance oversight has been on refiners that manufacture fuels at crude oil refineries with provisions that then attempt to ensure that the fuel quality as measured at the refinery is maintained all the way to retail. What happens at the 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 finished fuels (*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 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 parties are taking actions that can impact fuel quality downstream of the refinery, all in-use gasoline could benefit from a retail survey. Without it we could not implement 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 extending the retail survey that

[87] See Section VII.F.

has been applicable for over 20 years in RFG areas to all gasoline nationwide. The national in-use gasoline survey will 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 will also enable EPA to provide compliance flexibility to CG refiners and importers similar to RFG refiners and importers.

2. National Fuels Survey Program

a. Consolidation and Scope

We are finalizing the consolidation of the four in-use survey programs outlined in Table X.A–1 into a single national fuels survey program (NFSP). We believe the expanded scope of gasoline samples tested nationwide will help us ensure fuel quality oversight and compliance with EPA's applicable fuel quality standards in-use. This will also provide compliance flexibility for CG manufacturers to account for oxygenate (as discussed in Section VII.F). As previously explained, the ULSD and E15 survey programs under part 80 are national surveys of retail stations but only test for sulfur in diesel fuel and ethanol content and RVP of gasoline 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. Under part 80, 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, the required sample size of the NFSP under part 1090 could be reduced to less than 7,000 retail outlets sampled. Since the largest expense in retail surveying is the cost to collect and ship a sample from a retail station, reducing the sample size from more than 18,000 to less than 7,000 will substantially decrease the costs of the program.

The main benefit to EPA and the public is the expanded scope of testing for regulated fuel parameters to all fuel nationwide. Under the part 80 programs, 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, the gasoline properties tested for will also be consolidated. Sulfur, benzene, RVP (in the summer), and oxygenates will be tested for all the samples. A statistically determined subset of the national gasoline sample will 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 NFSP will also continue to ensure E15 pump labeling compliance at retail stations. For diesel samples, the survey will continue to test for sulfur.

We received several comments that supported this consolidation and most of those comments appreciated the reduced burden associated with the sample size reduction. We also received comments suggesting the removal of the verification of E15 compliance from the NFSP. We did not propose and are not removing the existing survey requirement for fuel and fuel additive manufacturers that make E15 or ethanol for use in making E15. Participation in this survey is mandatory under CAA section 211(f) and was established under CAA section 211(c) to ensure that E15 fuel dispensers are labeled correctly. We consider these comments outside the scope of this action.

b. Survey Participation

Gasoline manufacturers only need to participate in the NFSP if they choose to account for oxygenate added downstream in their compliance calculations. Under part 80, the RFG regulations imposed a similar survey requirement on RFG refiners and importers that accounted for oxygenate added downstream [88] and since we are now allowing this flexibility for manufacturers of CG, we are imposing 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 NFSP will satisfy one of the elements of an affirmative defense for downstream violations of our applicable fuel quality standards. Under part 80, we provide 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 NFSP 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 will continue to participate in the NFSP 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.[89] 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 finalizing as proposed that participation in the NFSP would satisfy the national survey option for purposes of compliance with the E15 waiver conditions or E15 substantially similar determination. The E15 waiver conditions and E15 substantially similar determination allow E15 fuel and fuel additive manufacturers to continue to use 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 will continue to elect to participate in the NFSP due to its significant cost savings.

c. Sample Sizes

For the NFSP, we are finalizing the proposed minimum sample size of 5,000 gasoline retail outlets and 2,000 diesel outlets. As outlined in the NPRM, 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

[88] See 40 CFR 80.69.

[89] See 75 FR 68094 (November 4, 2010), 76 FR 4662 (January 26, 2011), and 84 FR 26980 (June 10, 2019).

proposed the same sample size determination methodology that is used for those programs. This resulted in approximately 5,000 retail outlets since the existing survey program for E15 misfueling mitigation is national in scope. We also highlighted that since most retail outlets offer both gasoline and diesel fuel, the total number of retail outlets sampled could be closer to 5,000 retail outlets rather than 7,000 outlets. This is significantly lower than the 18,000 retail outlets required under part 80. We believe that it will maintain the statistical rigor of the existing part 80 programs while reducing costs. We received several supportive comments in the burden reduction associated with the consolidation of the part 80 survey programs into a single program. We did not receive any comments suggesting that we use a different sample size or sample size selection methodology.

For the subset of gasoline samples that would continue to be tested for the full suite of Complex Model fuel parameters, we proposed that the sample size would be determined using a standard calculation to estimate national fuel parameters. We estimated that around 1,200 gasoline samples would need to be analyzed for the full suite of Complex Model fuel parameters using this methodology. We received no comment suggesting an alternative methodology to calculate the number of gasoline samples that would be tested for the full suite of Complex Model fuel parameters, therefore, we are finalizing as proposed the requirement to test a subset of gasoline samples for all fuel parameters of the Complex Model and the methodology to determine the sample size of such gasoline samples.

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 must conduct the NFSP and meet similar independence requirements from parties that hire the surveyor to conduct the program. The independent surveyor is not allowed to have financial interest in companies that hire the independent surveyor to conduct the survey, nor are companies that hire the independent surveyor allowed to have a financial interest in the independent surveyor's organization. Like the part 80 survey programs, the surveyor must submit an annual plan for surveys conducted under part 1090 to EPA for approval. The plan must identify how the independent surveyor intends to meet the survey regulatory requirements and is subject to EPA approval prior to conducting the survey. Additionally, the independent surveyor must submit annually to EPA proof that the NFSP has been fully funded for the next compliance period by December 15. Except for comments that suggested that the employment criteria for independence should be shortened from three years to one year (discussed in more detail in Section XIII.A, we received no comments on the proposed requirements for the independent surveyor. Therefore, we are otherwise finalizing these provisions as proposed.

As part of our effort to modernize the fuel quality programs, we are requiring under part 1090 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 will help EPA more quickly provide information collected as part of the NFSP and promote greater transparency in the fuel quality program. The proposed reporting requirements for independent surveyors are similar to those currently specified in part 80, and the independent surveyor will need to keep records in a similar manner. We received no comments on our proposal to require independent surveyors to register with EPA and submit reports electronically and therefore are finalizing these provisions as proposed.

B. National Sampling and Testing Oversight Program

The RFG regulations in part 80 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. Since arranging to have an independent laboratory collect a sample is the most expensive part of the process, commenters argued that this requirement is unnecessarily burdensome. Part 80 also requires that every 33rd batch of RFG collected by an independent lab must be sent to EPA for analysis.[90] As part of consolidating the compliance provisions across the various gasoline and diesel fuel to create a single fuel quality program, and in light of the retirement of the Complex Model for batch certification and removal of various restrictions on the production and use of RFG, we considered how best to ensure proper EPA oversight of the sampling and testing for fuels compliance.

In lieu of the existing RFG requirements, we are finalizing the more flexible and less burdensome NSTOP as proposed. The purpose of this proposed program is to help ensure that fuel manufacturers are sampling and testing in a manner consistent with the required procedures discussed in more detail in Section IX.

As part of the NSTOP, we are requiring that the independent surveyor review appropriate PBMS qualification and SQC data for the samples collected and tested from gasoline manufacturers. We believe that this will help ensure that labs that test gasoline for compliance under our fuel quality programs are complying with EPA quality control provisions for labs.

Like the NFSP 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 requiring an estimated 500–750 samples to be collected as part of NSTOP annually. This compares to the several thousand samples currently collected from RFG refiners each year under the part 80 independent laboratory requirements. These samples would be spread across all gasoline manufacturers instead of just RFG refiners. This provides a substantial reduction in associated burden with independent sampling while still providing the necessary oversight.

We are finalizing the requirement that gasoline manufacturers that elect to account for oxygenate added downstream must participate in NSTOP. We believe this requirement will help ensure that fuel manufacturers are sampling, testing, and reporting results of gasoline that is representative of gasoline (*i.e.,* BOB) leaving the fuel manufacturing facility gate. We are also exempting refineries that have in-line blending waivers from NSTOP as proposed since these refineries must meet the annual audit requirement using an auditor.

Gasoline manufacturers that participate in the program will 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 requiring that an additional number of random samples be collected to ensure an effective deterrent against complacency

[90] 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.

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 will help ensure that gasoline manufacturers are following appropriate sampling and testing procedures year-round, even if sampled early in the season.

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, which totals between 300–400 RFG samples per year.[91] Under part 1090, we will no longer collect these oversight samples from RFG refiners and independent labs, as proposed. However, as part of the NSTOP, we are requiring that the independent surveyor send a random selection of samples collected to NVFEL for comparison to the results obtained from the independent surveyor and fuel manufacturer's lab. This will allow NVFEL to continue to serve as a reference installation and maintain EPA oversight of the NSTOP. We intend to collect a similar amount of gasoline samples, around 300 per year, as we currently receive under the RFG program. We received one comment noting that having NSTOP samples shipped to NVFEL would unnecessarily add costs to the NSTOP for little value. For reasons discussed in more detail in Section 16 of the RTC document, we are finalizing as proposed that some NSTOP samples be shipped to NVFEL.

Like the NFSP, we are requiring that an independent surveyor conduct the NSTOP. We envision that these parties would function similar to the way that independent surveyors operate under the part 80 survey programs. Therefore, we are requiring the same independence and plan approval process as those used for independent surveyors under the NFSP, which is similar to the part 80 survey requirements. The only difference would be a change in the reported elements as samples are collected from gasoline manufacturing facilities instead of retail stations. We did not receive any comments on this aspect of the NSTOP and are finalizing the requirements for independent surveyors conducting the NSTOP as proposed.

In the proposal, we also sought comment on whether to maintain the existing RFG independent laboratory testing requirement or whether to require that third-party laboratories that perform testing for fuel manufacturers under the NSTOP also register and associate. We received several comments suggesting that the RFG independent laboratory testing requirement was no longer necessary and that associated burdens with requiring all third-party laboratories to register and associate with fuel manufacturers would be cost prohibitive. We also received comments, mostly from third-party laboratories, noting that we should maintain the RFG independent testing requirement or require the registration of third-party labs as a means to help ensure the integrity of sampling and testing performed by third-parties for fuel manufacturers. For reasons discussed in more detail in Section 13 of the RTC document, we are finalizing as proposed the removal of the RFG independent lab testing requirement and are not finalizing a requirement that all third-party laboratories register and associate with fuel manufacturers.

A number of commenters included suggestions and requests for clarification regarding the NSTOP and we have reflected them in the final regulations as appropriate. We address these comments in Section 13 of the RTC document.

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 Q). As described in this section, importers will continue to be subject to the same requirements as refiners, while exporters will continue to be subject to certain fuel designation and recordkeeping provisions. Overall, we are making several changes to how imported and exported fuel products are treated relative to the provisions of part 80, although we are significantly updating the regulatory text. Many of the modified part 1090 provisions are merely codification of existing implementation policies summarized in a 2003 question and answer (Q&A) document (''2003 Q&A document'').[92]

A. Importation

With few exceptions, we are finalizing the proposed requirements under part 1090 for importers that largely mirror what we require under part 80. However, we are updating some provisions for imports in part 1090. First, importers that import fuel at multiple import facilities within a single PADD must aggregate the facilities within that PADD for purposes of complying with the maximum benzene average standard. For compliance with other average standards, importers will 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.[93]

Second, under part 80, current guidance allows gasoline classified as ''American Goods Returned'' to the United States by the U.S. Customs Service to not count as imported gasoline.[94] As proposed, we are finalizing 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 fuel manufacturing facility prior to being imported into the U.S.

We are not changing how importers are defined in part 1090 compared with part 80.[95] 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

[91] 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.

[92] 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.

[93] See 19 CFR part 151, subpart C.

[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] See 40 CFR 80.2(r).

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.

B. Special Provisions for Importation by Rail or Truck

We are finalizing as proposed the compliance options for meeting testing requirements when importing fuels by either rail or truck. These provisions allow importers via rail or truck to meet the sampling and testing requirements based on test results from the supplier instead of testing each batch after the fuel is imported, under certain conditions.

First, for gasoline, the truck or rail importer electing to use supplier test results must meet 0.62 volume percent benzene content and 10 ppm sulfur content per-gallon maximum standards. This requirement is identical to what is currently required under part 80.[96]

Second, the importer must get documentation of test results from the supplier for each batch of fuel. Testing for a given batch must occur after the most recent delivery into the supplier's storage tank and before transferring product to the railcar or truck.

Third, the importer must conduct testing to verify test results from each supplier, by collecting samples either once every 30 days or every 50 rail or truckloads of fuel from a given supplier, whichever is most frequent.

We received several comments that suggested that our proposal to allow added flexibility was forcing importers via truck and rail to comply with more stringent per-gallon standards. This was not our intent and we have revised the regulations to clarify that importers that import via truck or rail have the option to sample and test each batch of imported gasoline and comply with average benzene and sulfur standards or rely on test results from the gasoline supplier and meet a per-gallon standard. We address other comments related to imports by truck and rail in Section 18 of the RTC document.

C. Special Provisions for Importation by Marine Vessel

We are finalizing as proposed the provisions that specifically address importation of fuels by marine vessels. These provisions are generally the same as those addressed in the 2003 Q&A document.[97] Under part 1090, separate certification is 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 not allowing importers who import by marine vessels to rely on testing from a foreign source given our lack of jurisdiction generally. 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 provisions, different ship compartments would generally be considered different batches of fuel. However, we are allowing for the following exceptions. First, importers may 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 required for all composite samples. As is the case under part 80, importers must demonstrate that results for homogeneity testing fall within the specified range for the test method used(s) used to determine homogeneity. Under the updated homogeneity testing procedures in part 1090, this should 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 the decrease in the number of fuel parameters for homogeneity testing from as many as 11 under part 80 to two under part 1090. This change would result in a substantial decrease in testing burden.

Second, we will 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 if each individual vessel compartment is shown, through sampling and testing, to meet all applicable standards.

We received several comments suggesting edits and requesting clarifications to the part 1090 marine vessel import provisions that we have reflected in the final regulations as appropriate. We address these comments in Section 18 of the RTC document.

D. Gasoline Treated as Blendstocks

We are transferring part 80 provisions for gasoline treated as blendstock (GTAB) to part 1090 largely unchanged. We are also substantially reducing the number of parameters that are tested and reported to EPA for GTAB. Our primary concern with GTAB has been to ensure that off-spec gasoline imported into the U.S. is 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 EPA's fuel quality standards is based on sampling and testing the finished fuel and part 1090 no longer requires 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 must continue to be reported. Other provisions related to GTAB are consistent with current part 80 requirements and published guidance.

In general, comments were supportive of this proposal. However, we received some suggestions for clarification of the GTAB provisions that we have reflected in the final regulations as appropriate. We address these comments in Section 18 of the RTC document.

XII. Compliance and Enforcement Provisions and Attest Engagements

A. Compliance and Enforcement Provisions

We are finalizing the compliance and enforcement provisions as proposed with one exception. We are also finalizing lower sulfur and benzene default values that will apply to sampling and testing requirements violations for fuel content standards.

As explained in the NPRM, the 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 it difficult for EPA and the public to know if the fuel meets the applicable standards. Several commenters suggested that the proposed levels, which were identical to the levels in part 80, were too high. The commenters suggested that the default values had not been updated in over 25 years and were not reflective of modern fuel manufacturing. Several commenters

[96] See 40 CFR 80.1349 and 80.1641. It should also be noted that under part 1090 we are allowing these provisions to be used for rail imports in addition to the currently allowed truck imports under part 80. Under part 1090, diesel fuel is only subject to per-gallon standards, so alternative standards to diesel fuel imported via rail or truck are not necessary.

[97] 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.

suggested default levels that were at or below EPA's regulatorily specified levels. We believe that it would be inappropriate and counterproductive to assume that fuels, fuel additives, and regulated blendstocks met EPA's fuel quality standards if a party failed to appropriately sample and test for compliance. Such levels would provide a strong incentive for parties to forgo compliance sampling and testing altogether, which would jeopardize fuel quality. Other commenters suggested more modest reductions in the default values, but no commenter provided compelling data to support alternative default values.

However, we acknowledge that fuels are made and distributed differently today than they were when we promulgated the part 80 default values in the 1990s. Therefore, we have chosen to use the sulfur and benzene levels specified in CAA section 211(k)(10)(B) for summer (339 ppm sulfur) and winter (1.64 volume percent benzene) baseline fuel, respectively.[98] We believe these values represent fuels prior to the promulgation of current EPA fuel quality standards, which have controlled sulfur and benzene contents to their current regulatory levels (10.00 ppm and 0.62 volume percent, respectively).

The final rule provides that if a fuel, fuel additive or regulated blendstock manufacturer fails to comply with the sampling and testing requirements, the gasoline will be deemed to have the parameters in Table XII.A–1 below, 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.

TABLE XII.A–1—DEFAULT VALUES FOR FUEL, FUEL ADDITIVE, AND REGULATED BLENDSTOCK PARAMETERS

Product	Sulfur value (ppm)	Benzene value (volume percent)	RVP value (psi)
Gasoline	339	1.64	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	339	n/a	n/a
Regulated Blendstocks	339	1.64	n/a

As mentioned above, the default values approximate uncontrolled levels prior to promulgation of current EPA fuel quality standards and create an additional incentive for fuel, fuel additive and regulated blendstock producers to properly sample and test gasoline and ensure that they will not benefit by underreporting the sulfur, benzene, or RVP of gasoline that is not properly sampled or tested. For fuel manufacturers that produce gasoline using the PCG by subtraction approach, the default values for sulfur is 0 ppm and the default value for benzene is 0 volume percent. This approach attributes all sulfur and benzene to the added blendstock and provides incentives for a blending manufacturer to appropriately sample and test the PCG.

In addition to the comments received on default values, one commenter asked for additional detail regarding how to inform EPA about a failure to comply with the sampling and testing requirements and what type of information EPA will consider when determining whether to approve a value that is different than the default values. Regulated parties should inform EPA of a failure to comply with the sampling and testing requirements through EPA's eDisclosure portal.[99]

The determination about whether to approve a request to use an alternative value will be made on a case-by-case basis. EPA will consider all relevant information in making this determination, including but not limited to engineering analyses and results from tests that do not meet the regulatory standards.

We address comments related to the compliance and enforcement provisions in more detail in Section 19 of the RTC document.

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 the various existing attest requirements in part 80 to a single subpart in part 1090 (subpart S). 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 have added a requirement for auditors to review the fuel manufacturer's calculations showing that they comply with the sulfur and benzene average standards. We note that EPA's Office of Inspector General made certain findings and recommendations regarding compliance with these standards as part of their review of the auditing requirements under part 80.[100] One recommendation was to modify the attest engagement regulations to require that auditors verify compliance calculations for gasoline manufacturers to help ensure that the benzene average standard was met. We believe the revised attest engagement provisions are consistent with this recommendation and will provide better oversight of the gasoline sulfur and benzene average standards.

We are also codifying the existing attest requirements spelled out in the 2003 Q&A document.[101] We are adopting these requirements for both CG and RFG. The most significant new provision is 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 require a relatively straightforward review by auditors of whether labs used to test gasoline for

[98] We choose the summer baseline for sulfur as it was 1 ppm higher (339 ppm for summer versus 338 ppm for winter) and the winter baseline for benzene as it was 0.09 volume percent higher (1.64 volume percent for winter versus 1.53 volume percent for summer).

[99] See *https://www.epa.gov/compliance/epas-edisclosure.*

[100] 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.

[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.

compliance have records demonstrating that their 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 requiring 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 require that the independent surveyor review this type of information under the NSTOP.) We do not believe that this simple review will greatly increase the burden associated with the annual attest audits. We believe this laboratory record review will help ensure that labs used for testing fuels for compliance are doing so consistent with EPA's quality control requirements helping to ensure a level playing field and program integrity.

We received several comments that suggested edits to the proposed regulations and asked for clarification on the various attest engagement provisions that we have reflected in the final regulations as appropriate. We address these comments in Section 20 of the RTC document.

C. RVP Test Enforcement Tolerance

Under part 80, EPA recognizes and allows a 0.3 psi downstream enforcement test tolerance over applicable RVP standards for RVP test results.[102] This test tolerance was based on RVP testing variability and the reproducibility of the test methods at the time the RVP standards were established. Under this approach, we rely on test results from locations downstream of fuel manufacturing facilities to bring enforcement actions against downstream parties only if the downstream test results are more than 0.3 psi above 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 gasoline manufacturer'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.

We are continuing 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 will 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 finalizing 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 requirements are consistent with part 80 independence and technical competency requirements for independent third-parties. We believe the requirements will preserve and strengthen the integrity of our independent third-party verification programs.

We remain concerned 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. Therefore, we are maintaining 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 clarifying that independence requirements apply not only for the third parties and their employees, but also for any contractors and subcontractors.

Similar to part 80, we are imposing restrictions on both employment history and financial interest. We proposed 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.

We are also finalizing 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 requested 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. We have adopted some of the suggested changes and have addressed these comments in Section 4 of the RTC document.

Part 1090 also includes 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.[103] These provisions ensure that program oversight is being conducted by parties with the requisite technical capabilities. However, we do not currently require this demonstration under part 80 for in-use surveys. Under part 1090, we are requiring that the independent surveyors 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 are unchanged in part 1090.

Several commenters suggested that the technical qualification requirements were too restrictive. First, commenters suggested that the requirement that independent parties could not provide services that require independence until 3 years after the point when the independent party was last employed by the regulated party was too long and would result in a significant constraint on the availability of technically competent auditors and surveyors. Based on these comments, we reduced the 3-year period to a 1-year period as commenters suggested. Second, one commenter suggested that the technical competency requirement for a lab to qualify non-VCSB methods was too strict and could not be fulfilled by a single person. We are finalizing these provisions as proposed since we believe that a laboratory that is going to qualify

[102] 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.

[103] See 40 CFR 80.92 and 80.1469.

non-VCSB methods must have appropriate personnel to evaluate the new method. We have addressed these comments in Section 4 of the RTC document.

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 dispenser labeling requirements) into one subpart (subpart P) with only minor changes (including removing several obsolete provisions from part 80). We are finalizing, as proposed, the description of the E15 label by replacing descriptive paragraphs with a graphic example of the E15 pump label. We believe these changes will make the regulations easier to identify and follow for retailers and WPCs.

We are finalizing minor modifications to the existing label language for heating oil by removing the now obsolete label language identifying that the heating oil contains greater than 500 ppm sulfur.[104] Most heating oil sold today meets state 15 ppm sulfur standards, and we believe that it is now 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 allowing retailers to continue to use existing labels to satisfy the part 1090 labeling requirements until such time as 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. However, if there were situations where ECA marine fuel is co-dispensed with other fuels, a label might still help avoid the misfueling of diesel engines that require the use of ULSD with ECA marine fuel. We proposed to maintain the existing part 80 label requirement but requested 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 received no comments on this question, so we are maintaining the ECA marine fuel labels that are currently required under part 80.

[104] See 40 CFR 80.573.

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 updated nozzle requirements for refueling motor vehicles are aligned with the requirements adopted under part 80. There is one noteworthy adjustment. We 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 updated specifications, including rounding, are 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 do not need to be modified.

Similar nozzle requirements apply for dispensing gasoline into marine vessels. We are similarly adopting a singular set of nozzle-geometry specifications in millimeters in a way that is aligned with the specifications as originally adopted. We are also concluding 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 now require that they be replaced with a nozzle that meets the standardized configuration. This requirement applies January 1, 2021, when part 1090 becomes effective.

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 proposed 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. However, based on a comment received, we are deferring action on this item. As we are not taking any final action on that provision in this action, the regulations at 40 CFR 80.24 remain unchanged. We intend to revisit this issue in a future rulemaking related to vehicle standards.

D. Previously Certified Gasoline (PCG)

We are largely maintaining the existing part 80 provisions for how blending manufacturers may make new batches of gasoline from PCG and blendstocks.[105] In the Tier 3 rule, we finalized changes to improve the consistency of the PCG provisions across part 80 programs;[106] however, we maintained separate PCG provisions for each part 80 gasoline program. In part 1090 we are consolidating these provisions into a single set of PCG provisions that maintain both options used in part 80: (1) PCG by subtraction; and (2) PCG by addition.[107] Other 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 received several comments related mostly to how to address various scenarios where blendstocks are added into PCG that has been identified for oxygenate blending by the original PCG manufacturer. For example, commenters requested clarification on whether a party that adds blendstock to PCG must account for the fact that the PCG was intended to have oxygenate added to it. In response to these comments, we are modifying the PCG provisions to ensure that oxygenate is accounted for properly.

Several commenters also suggested edits and clarifications to the part 1090 regulations and have made edits to the regulations where appropriate to address these comments. We address these comments in Section 21 of the RTC document.

[105] The purpose of allowing parties to make new batches of gasoline using PCG is to provide flexibility for parties making new fuels to accommodate market demands while ensuring that the fuel quality standards are met. The provisions are designed to ensure that the new batch meets gasoline per-gallon standards and that the blending manufacturer does not increase the average sulfur and benzene levels in the national gasoline pool.

[106] See 79 FR 23575–23576 (April 28, 2014).

[107] 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 will need to sample and test for sulfur year-round and for RVP in the summer.

E. Transmix and Pipeline Interface Provisions

With few exceptions, we are finalizing the proposed requirements under part 1090 for transmix processors that largely mirror what we require under part 80. In part 1090 we are consolidating and simplifying the flexibilities provided to fuel manufacturers that use transmix to produce gasoline and diesel fuel, and are aligning the requirements applicable to these parties to the requirements applicable to other fuel manufacturers under part 1090.[108] 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 [specified] sampling and testing requirements and standards instead of the sampling and testing requirements and standards otherwise applicable to a refiner under this subpart O.'' [109] 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.

1. Clarifying and Consolidating Requirements Relating to Transmix and Pipeline Interface

Provisions related to the treatment of transmix are currently located in various sections in part 80.[110] To improve clarity, we have consolidated most of the special provisions related to the treatment of transmix into a single subpart in part 1090 (subpart F). We also incorporated 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.[111]

2. Blending Transmix Into Previously Certified Gasoline

In part 1090 we made a minor change to the requirements that apply to parties that blend transmix into PCG.[112] 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 were temporarily required under part 80 to conduct more frequent sampling and testing. We changed this requirement so that no more than one sample per day may be used to demonstrate compliance with this increased testing requirement. This change in part 1090 will ensure that the required increase in sampling and testing frequency fulfills the intended purpose of verifying that the issue(s) that caused the violation have been resolved.

3. Gasoline Produced From Transmix Gasoline Product

As proposed, we are consolidating the different RFG and CG provisions that apply to transmix processors into one set of provisions that largely mirrors the part 80 transmix provisions. Transmix gasoline product, or TGP, is the gasoline blendstock that is produced when transmix is separated into blendstocks at a transmix processing facility. The part 1090 regulations require transmix processors and blending manufacturers that produce gasoline with TGP to exclude the volume of TGP and PCG used to produce gasoline from their annual compliance calculations for the sulfur and benzene average standards. Parties that produce gasoline with TGP and other blendstocks must follow the PCG procedures to account for the sulfur and benzene levels of the added blendstocks for demonstrating compliance with annual average sulfur and benzene standards. Transmix processors and blending manufacturers that only produce gasoline from TGP or TGP and PCG are deemed to be in compliance with the sulfur and benzene average standards. In all cases, fuel manufacturers that produce gasoline using TGP must 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. If transmix processors can demonstrate that the transmix and any blendstock they use to produce gasoline contain no oxygenate, they are not be required to test the gasoline they produce for oxygenate content.

Based on suggestions from commenters, we are also finalizing provisions that will allow for TGP to be transferred from a transmix processor to another fuel manufacturer to be used to produce gasoline. The transmix processor will use a PTD that designates the product as TGP and note that it is not suitable for use as gasoline. In such cases where TGP is blended to produce gasoline, the TGP is treated as PCG (*i.e.,* the blending manufacturer must take steps to ensure that the sulfur and benzene content from the TGP is excluded from their average standard compliance demonstrations).

4. 500 ppm LM Diesel Fuel Produced From Transmix

We are finalizing as proposed the 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, with one exception. One commenter pointed out that since part 1090 requires all volume measurements to be temperature adjusted, thermal expansion should not result in differences between the volume of 500 ppm LM diesel fuel received versus the volume delivered and used on a compliance period basis. We agree with this comment and removed this as an allowable justification for volume differences.

5. Streamlining the Requirements for Pipeline Interface That Is Not Transmix

We are finalizing the regulatory provisions that allow pipeline operators to 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 than were imposed under part 80. During the winter months there are no restrictions relating to how operators cut pipeline gasoline interface. 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, pipeline operators may not cut pipeline interface from a batch of RFG shipped adjacent to a batch of CG into the batch of RFG.

F. Gasoline Deposit Control

1. Overview

We are finalizing streamlined and updated regulations for gasoline deposit control. 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

[108] Refiners that produce gasoline and diesel fuel by processing crude oil must not use the provisions that apply to transmix processors and are subject to all requirements that apply to a fuel manufacturer.

[109] See 40 CFR 80.1607.

[110] See 40 CFR 80.84, 80.213, 80.513, 80.840, and 80.1607.

[111] See 40 CFR 80.84.

[112] 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.

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.[113] 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.[114]

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.[115] 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 provided by the detergent program today.

At the same time, there is considerable cost and effort associated with continuing to implement the detergent program. Consequently, we are streamlining the program to the extent possible to minimize its cost. Specifically, we are: (1) Eliminating the requirement that a detergent that is demonstrated to control intake valve deposits must also be tested to demonstrate the ability to control fuel injector deposits; (2) easing the adoption of updated deposit control test procedures when they become available; (3) simplifying the process for registration and certification of detergents and the demonstration of compliance by detergent blenders; (4) removing expired and unused provisions; and (5) removing the requirement that the gasoline portion of E85 must contain a certified detergent. In response to several comments, we are finalizing testing requirements for new detergents consistent with part 80 requirements that will maintain the specifications for detergents, while updating them to accommodate new circumstances discussed in this section. The following sections detail the changes we are finalizing.

2. Eliminating the Port Fuel Injector Deposit Control Testing Requirement

We are finalizing our proposal to eliminate the requirement that detergents be tested to demonstrate the ability to control port fuel injector deposits. We received several comments in support of this proposal. This change will substantially decrease the burden of introducing new detergents while maintaining the benefits of the detergent program.

Under part 80, we required 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 and from comments supports the conclusion that detergents that are capable of controlling intake valve deposits are inherently capable of controlling port fuel injector deposits.[116] 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 used a 1985–1987 Chrysler 2.2L vehicle.[117] The fuel injector technology used in these old 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 (discussed in the next section) 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 antiquated and of questionable relevance to the in-use fleet today. New detergents under part 80 are tested using the EPA ASTM D5500 BMW-based deposit control test procedure (''EPA ASTM D5500 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 35-year-old vehicle is no longer representative of the technology used in modern vehicles.[118] 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.[119]

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.[120] 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 market shifts. 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. 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

[113] See 61 FR 35310 (July 5, 1996).

[114] Under part 80, this period can be up to 30 days. Part 1090 does not change this period.

[115] 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.

[116] 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.

[117] 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.

[118] CRC Gasoline Engine Deposit Task Group, CRC Project No. CM–136, CRC Annual Report, September 2018.

[119] Id.

[120] 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.

finished gasoline.[121] 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.[122]

Consequently, we proposed to disallow new detergents that had established a lowest additive concentration (LAC) through the EPA ASTM D5500 procedure. We proposed that new detergent deposit control testing could be conducted using the Top Tier program or California's deposit control program.[123] We also proposed that existing detergent certifications based on the EPA ASTM D5500 procedure would remain valid indefinitely while new testing procedures could be adopted with EPA-approval.

Several commenters suggested that the proposal to disallow new additives tested on the EPA ASTM D5500 procedure would constitute a de facto change in the stringency of the part 80 deposit control standards, which would result in a substantial increase in costs to industry. While we believe that the commenters may have overstated the expected costs, especially considering that we proposed that previously tested detergents under EPA ASTM D5500 would remain valid indefinitely, we agree that the removal of the option to test new detergents using the EPA ASTM D5500 procedure could result in a slight increase in the stringency and cost for new deposit control formulations. As such, we will continue to allow the EPA ASTM D5500 procedure to be used to certify new detergent formulations.

4. Expanding the Applicability of Detergent Certifications Based on Compliance With the California Deposit Control Regulations

Under the part 80 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 if 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 gasoline that does not meet California requirements. When EPA's detergent program was finalized in 1996, the composition of gasoline that complies with California standards differed substantially from gasoline that met EPA's requirements.[124] 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 EPA's program allows the accumulation of up to 100 mg per valve using the EPA ASTM D5500 procedure. Consequently, we proposed that a detergent certified under California's program could be used to meet EPA's deposit control requirements in all gasoline. Comments received were supportive, as long as we continued to allow for new detergent testing to be done on the EPA ASTM D5500 procedure. As such, we are finalizing the proposal to allow California detergent testing to be used to satisfy EPA detergent testing requirements.

5. Easing the Adoption of Future Updates To Deposit Control Test Procedures

We are finalizing provisions that allow for an administrative process to approve new deposit control test protocols in a streamlined manner. In the proposal, we co-proposed 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.

We are finalizing the primary approach, which allows for deposit control test procedures accepted by EPA to be specified in a publicly available document that could be updated as EPA accepts new procedures.[125] The use of this streamlined process will 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 administrative process.

Under this approach, stakeholders may 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 will 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 meets applicable regulatory requirements, we will publish on our web page and by direct communications with stakeholders that we have accepted the change. We may also periodically update the detergent regulations in the CFR to reflect accepted alternatives.

Comments received were supportive of EPA providing added flexibility to approve new detergent testing protocols via an administrative process. Therefore, we are finalizing the primary approach as proposed.

6. Removing Expired and Unused Provisions

We are finalizing the removal of expired and unused provisions in the detergent program to make the detergent regulations more accessible, understandable, and to eliminate the ongoing costs of maintaining these provisions.

The detergent program in part 80 includes provisions allowing a detergent to be certified for use in different gasoline pools using test fuels that have specifications representative of the deposit-forming characteristics of the 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.[126] We also accept detergent certifications under the California program in lieu of meeting our requirements. Since all applications for

[121] See 65 FR 6698 (February 10, 2000) and 82 FR 23414 (April 28, 2014).

[122] The approved sulfur doping compound is di-tertiary di-butyl sulfide.

[123] See Title 13, California Code of Regulations, Section 2257.

[124] See 61 FR 35326–27 (July 5, 1996).

[125] It is worth noting that the test protocols will be compared to a baseline established by the EPA ASTM D5500 procedure using the part 80 test fuels. This baseline was adopted since that was the baseline for determining the deposit control specifications under CAA section 211(l).

[126] See 40 CFR 80.163.

detergent certification to date other than those based on the California program have been under the national-generic option we are removing the other options. 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 will 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 will also remain valid.[127]

We are also removing regulatory provisions associated with the interim detergent program that were superseded by the detergent program in 1996.[128] Comments received on this aspect of the proposal were supportive, and we are therefore finalizing the removal of expired and unused provisions as proposed.

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 EPA's deposit control requirements. To speed up the introduction of new detergents and to reduce the burden of detergent certification, we are allowing detergent manufacturers to begin marketing a detergent once the manufacturer has satisfied EPA testing requirements without the need for a prior submission of the data to EPA and approval by EPA. Under this approach, detergent manufacturers will still 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 part 79. Additional composition information is also required for detergents to be evaluated for deposit control efficacy under part 80, including the LAC established by detergent deposit control testing. In lieu of requiring a separate submission of this additional information under part 1090, we are requiring it to be submitted with a detergent's part 79 additive registration. Comments on this aspect of the proposal were supportive and we are finalizing the provisions as proposed.

8. Simplifying the Detergent Volumetric Accounting Reconciliation Requirements

Under parts 80, 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; this is not changing under part 1090. However, under part 80, the VAR provisions require that detergent blenders compile a separate record for each monthly VAR period in a standard format. During the rule development process, 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 represented a significant burden. To reduce the burden, we proposed to remove the requirement that a VAR report be prepared for each accounting period. This 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. We also proposed 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. All comments received on the proposal to simplify VAR requirements were supportive, and we are finalizing these provisions as proposed.

9. Removing the Requirement That the Gasoline Portion of E85 Contain Detergent

We are finalizing an exemption to the deposit control requirement for the gasoline portion of E85. The part 80 deposit control regulations require that the gasoline portion of E85 must contain a detergent additive at or above the LAC.[129] 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.[130]

In the REGS rule, we noted that we were 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 instead contribute to deposit formation. We also noted that certain detergents may not be 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.

In the NPRM, we explained that this action is allowable because 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.[131] All comments received on this aspect of the proposal were supportive and we are finalizing these provisions as proposed.

G. In-Line Blending Waivers

Under part 1090, we will continue the policy of approving in-line blending waivers. These waivers allow refiners 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 that we have consolidated into a single set of requirements for in-line blending in part 1090. For RFG manufacturers, the in-line blending requirements remain largely unchanged except that RFG manufacturers' in-line blending waivers need not cover parameters no longer required for certifying batches of gasoline (discussed in more detail in Section V.A.2). RFG manufacturers will 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 manufacturers, we will allow in-line blending waivers to cover all regulated gasoline parameters instead of just sulfur. CG refiners will also have to undergo the same annual audit procedure that currently exists for RFG refiners under part 80. The flexibility to cover additional parameters for CG refiners through the in-line blending waiver should far exceed any costs associated with the additional audit.

[127] See Section XIII.F.4 regarding the expansion to the applicability of California-based detergent certifications.

[128] See 40 CFR 80.141 through 80.156.

[129] See 40 CFR 80.161(a)(3).

[130] See 81 FR 80828 (November 16, 2016).

[131] See 40 CFR 79.56(e)(1)(i) regarding the gasoline family definition. See ASTM D5798 regarding the ethanol content of E85.

Due to the substantial changes in part 1090 to the requirements for in-line blending waivers, we are requiring all gasoline manufacturers with existing in-line blending waivers to resubmit their in-line blending waiver requests. This will help to ensure that in-line blending waivers appropriately cover the new requirements. Gasoline manufacturers must have EPA-approved updated waiver requests by January 1, 2022. This allows time for refiners to prepare new submissions and for EPA to review and approve those submissions. Note that diesel fuel manufacturers with an existing in-line blending waiver do not need to submit new requests for diesel fuel under part 1090 and may continue to operate under their part 80 in-line blending waiver.

Several commenters expressed concern regarding in-line blending waivers for locations that are blending into tanks. We did not intend to disallow in-line blending into tankage and the part 1090 regulations have been updated to address this concern. We further address these comments in Section 21 of the RTC document.

H. Confidential Business Information

We are finalizing regulations that will 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. The regulations 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.'' [132] 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.[133]

In June 2019, the U.S. Supreme Court issued its decision in *Food Marketing 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.'' [134] The Court identified two conditions ''that might be required for information communicated to another to be considered confidential.'' [135] 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.*[136] 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.[137]

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. In particular, this decision applies to requests under the following processes: R&D testing exemptions under 40 CFR 1090.610, hardship exemptions under 40 CFR 1090.635, alternative quality assurance programs under 40 CFR 1090.500, alternative PTD language under 40 CFR 1090.1125, 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 improve processing of information requests and increase transparency related to EPA determinations, we are clarifying 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. 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.[138] For information submitted under part 1090 claimed as confidential that is outside the categories described above, and not specified in the regulations at 40 CFR 1090.15(b) or (c), EPA will evaluate such confidentiality claims in accordance with *Argus Leader* and 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. Given the fungible fuel supply, and the resulting impacts of fuel quality specifications on emissions and emissions control systems when fuels are used in vehicles and engines, the regulations we are

[132] 5 U.S.C. 552(b)(4).

[133] We note that CAA section 114 explicitly excludes emissions data from treatment as confidential information.

[134] *Argus Leader,* 139 S. Ct. at 2366.

[135] Id. at 2363.

[136] ''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.*

[137] 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.*

[138] We note that this list does not convey the entire scope of information that we may release. Other information that does not meet the legal requirements for confidential treatment can also be released despite not being listed here.

finalizing in this action will better inform the public about exemptions to EPA's fuel quality regulations under part 1090 and will allow for the timely release of basic information relating to the requests. In particular, exemptions granted under part 1090 could result in higher levels of sulfur, benzene, or RVP in fuel, as well as changes in other fuel properties, which can have direct impacts on human health and the environment or on the functioning of vehicles, engines, and their emissions control systems. 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.

We received comments suggesting that our treatment of this basic information should be maintained as CBI if so claimed by submitters. Commenters suggested that refineries would have to choose between regulatory relief and release of information that may harm the refinery's reputation or finances. Commenters also suggested that the regulatory relief was specifically promulgated to help entities, and that disclosing information about the refinery would instead result in harm. We find that establishing the potential release of this basic information through regulation appropriately balances the interest in transparency for the public and the protection of information that could harm a refinery's reputation or finances. As noted above, providing the public with information about exemptions and flexibilities will maintain confidence in EPA's regulatory programs assuring fuel quality and expedite the process for the release of this information. It will also better inform the public about the use of these exemptions and flexibilities given the wide use of fuel and its impacts on air quality and engines and equipment. We note that post-*Argus Leader* substantial competitive harm is no longer the standard for evaluating whether information is confidential within the meaning of Exemption 4, and we are prospectively, via rulemaking, providing that we will not provide this specific information with confidential treatment. Additionally, we disagree with commenters that the disclosure of this information would necessarily result in harm. For many of the flexibilities mentioned above, the mere fact of a request is not often claimed as CBI (*e.g.,* alternative labels or PTD language), and commenters have provided no explanation as to why the disclosure of the fact of a request for these non-hardship regulatory flexibilities and EPA's response could result in harm. For extreme, unusual, and unforeseen hardship exemptions, as discussed in Section VI.A, the conditions under which a refinery can request extreme, unusual, and unforeseen hardship relief going forward are limited (*e.g.,* for natural disasters or refinery fires), and would very likely be known to the public such that the release of the fact of a request and EPA's decision would not result in reputational or financial harm to the refinery. Additionally, the public interest in the release of information relating to fuel quality is high, particularly when, as discussed above, increases in sulfur, benzene, and RVP, or changes in other fuel properties, have direct impacts on human health, the environment, and the functioning of vehicles, engines, and their emissions control systems. Commenters suggested, without any further explanation as to why, that the mere fact of a petition for relief would have ''tremendously negative effects on the submitter's competitive petition'' and that ''[c]ompetitors could seize upon the company's identified vulnerabilities to gain a competitive advantage through any number of methods.'' [139] In addition to failing to clearly articulate why or how the release of the fact of a petition would result in harm, commenters have not articulated why the basis for relief would not already be known in light of the remaining justifications available for hardship relief under part 1090 (*i.e.,* extreme, unusual and unforeseen hardship relief).

Commenters suggested that this action contradicts Congress's intent in providing provisions for hardship relief and that Congress must amend the CAA to allow for the release of this information. However, the opportunities for regulatory relief under part 1090 are not statutorily prescribed, nor is the confidential nature of the fact of a petition for relief or EPA's decision on it provided in the CAA. Commenters pointed to no CAA text that would suggest otherwise.

Commenters suggested that EPA has treated requests for regulatory relief as confidential for many years. While EPA has treated some requests as confidential, particularly some small refinery hardship exemptions under the RFS program,[140] historically EPA has also disclosed other types of hardship exemption decisions and names of parties who have received exemptions and other regulatory flexibilities.[141] Regardless of our past treatment of submissions, future submissions under part 1090 will be subject to the provisions laid out in this rulemaking, and will result in the potential disclosure of the information described above.

As stated above, EPA will continue to evaluate other information submitted to EPA and claimed as CBI and not articulated in 40 CFR 1090.15(b) and (c) in accordance with *Argus Leader* and our regulations at 40 CFR part 2, subpart B.

XIV. Costs and Benefits

A. Overview

In general, we expect that this action will reduce the cost of fuel distribution by improving fuel fungibility, reducing the costs for regulated parties to comply with our fuel quality regulations, and reducing the costs for EPA to implement these regulations. We do not expect a measurable effect on regulated emissions or air quality as this rule does not change the stringency of EPA's fuel quality standards. This section lays out the general areas of potential cost savings for producing fuels that we believe will result from this action.[142]

B. Reduced Fuel Costs to Consumers From Improved Fuel Fungibility

A number of the provisions being finalized in part 1090 are expected to improve fuel fungibility. This should result in decreased costs associated with the distribution and sale of such fuels. Some examples of ways that this should result in potential cost savings are 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, we are unable to quantify these

[139] Comments from Small Refineries Coalition, Docket Item No. EPA-HQ-OAR-0227-0080.

[140] See, *e.g., https://www.epa.gov/fuels-registration-reporting-and-compliance-help/rfs-small-refinery-exemptions,* which provides only aggregated information.

[141] See, *e.g.,* press release regarding hardship exemptions from the sulfur standards, available at: *https://archive.epa.gov/epapages/newsroom_archive/newsreleases/d07550f8d366e3c485256b1300637472.html.*

[142] We outline in more detail these areas for savings in the technical memorandum, ''Economic Analysis: Fuels Regulatory Streamlining Final Rule,'' available in the docket for this action.

types of costs savings. In the proposal, we sought comment on these potential areas of savings and information that might enable quantification. While commenters generally supported the provisions that allowed for improved fungibility, we did not receive any comments that provided any additional information or analysis to support the quantification of benefits from improved fungibility. Therefore, we have not quantified the savings from the improved fungibility of fuels as a result of this action.

C. Costs and Benefits for Regulated Parties

We anticipate that the streamlined fuels provisions in part 1090 will significantly reduce the administrative burden for regulated parties to comply with EPA's fuel quality standards. The opportunities to reduce such administrative burden have been discussed throughout this action. Some examples of areas where savings will 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 (discussed in Section X.A).

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.[143] As part of this action, we are replacing the multiple existing ICRs for part 80 into a single ICR for all fuel quality programs that are now 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 new ICR. This results in a burden reduction of about $10.7 million per year. Furthermore, there are additional areas of potential administrative savings for industry that may not be captured in ICRs.[144] We estimate these savings to be about $29.7 million per year. Including the $10.7 million cost reductions estimated under the ICR, the total estimated savings in administrative costs to industry is $40.4 million per year. Table XIV.C–1 outlines the categories identified for savings.[145]

TABLE XIV.C–1—ESTIMATED ANNUAL COST SAVINGS BY SAVINGS CATEGORY [a]

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	15.2
Information Collection Request	10.7
Total Savings	40.4

[a] 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 will be less time and effort for staff to understand and be trained on EPA's 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 making changes to the stringency of the fuel quality standards, we do not expect fuel manufacturers to have to alter their production processes in order to comply with part 1090. In prior fuels rulemakings, retooling crude oil refineries often serves as the most significant costs associated with changes in fuel quality standards. Similarly, other parties in the fuel distribution system are not 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 small one-time costs associated with updating recordkeeping and reporting systems and practices associated with the modified regulations. For example, parties will 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.[146]

Overall, we expect the savings from increased fungibility of fuels, the decrease in administrative costs, and other indirect cost savings resulting from the modified regulations to far exceed any one-time administrative costs needed to begin compliance with part 1090. These cost savings are expected to be passed along to consumers in the form of lower fuel prices, given the highly competitive fuels marketplace.[147] 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.[148]

TABLE XIV.C–2—ESTIMATED NET PRESENT VALUE COST SAVINGS [a]

Three percent discount rate (in millions)	Seven percent discount rate (in millions)
$715	$479

[a] Cost savings in 2019 dollars.

D. Environmental Impacts

Since we are not making 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 this action, there are certain areas where changes to compliance requirements could be viewed as marginally affecting in-use fuel quality.[149] These marginal changes could then have a ripple effect on regulated emissions. In general, such changes are very small, typically well below the levels that we have historically attempted to quantify in rulemakings where we establish fuel quality 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

[143] The supporting statement for the ICR and other supporting materials are available in the docket for this action.

[144] These savings are discussed in the technical memorandum, ''Economic Analysis: Fuels Regulatory Streamlining Final Rule,'' available in the docket for this action.

[145] Id.

[146] The ICR supporting statement is available in the docket for this action.

[147] We discuss many of these areas, including a much more detailed analysis of the cost savings, in the technical memorandum, ''Economic Analysis: Fuels Regulatory Streamlining Final Rule,'' and the ICR supporting statement, available in the docket for this action.

[148] These results are discussed in more detail in the technical memorandum, ''Economic Analysis: Fuels Regulatory Streamlining Final Rule,'' available in the docket for this action.

[149] In the NPRM we identified those areas that had the potential to have an effect on in-use fuel quality. These areas included whether the proposed RFG maximum RVP per-gallon standard of 7.4 psi was too high, whether allowing CG manufacturers the ability to account for oxygenate added downstream would slightly increase average in-use sulfur and benzene levels, and whether making compliance with EPA fuel requirements less burdensome would result in a number of new, less sophisticated fuel manufacturers that would be less likely to comply with EPA fuel quality standards. We also noted that the improved oversight, especially through third-party surveys, may improve the quality of fuel sold at retail and that by simplifying and modernizing our reporting requirements information would be more readily available to better enable the fuel quality oversight.

the overall air quality effects that will result from this action.

We sought comment on the potential effect of this action on fuel quality and we did not receive any adverse comments on potential fuel quality issues. We believe the streamlining of the fuel quality programs will 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 improved oversight mechanisms will allow us to better oversee compliance with the current fuel standards and take appropriate action when issues are identified. The net result of this may 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 Final Rule,'' is available in the docket.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action. This analysis, ''Economic Analysis: Fuels Regulatory Streamlining Final Rule,'' is available in the docket.

C. Paperwork Reduction Act (PRA)

The information collection activities in this 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 2607.02. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The information collection activities include 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 case 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 fuel dispenser labels.

The information collection for part 1090 will not result in duplication of requirements under existing part 80, as this action will replace nearly all non-RFS provisions under part 80. Part 1090 represents a change from part 80 that will significantly reduce many recordkeeping and reporting burdens associated with complying with EPA's fuel quality standards, including:

- A reduction in the number of unique fuels compliance reporting forms from 30 to six;
- A change in the frequency of batch reporting from quarterly to annual;
- A reduction in the parameters or properties required to be tested and reported, from 13 to four;
- Improvements to forms and procedures to make them more intuitive and remove duplication; and
- A consolidation and updating of PTD and attest engagement requirements.

Most respondents are already registered under part 80 and will not have to re-register under part 1090. The exact information collection requirements in this final rule are tied directly 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 registration, reporting, sampling, testing, recordkeeping, survey, and attest engagement responsibilities; whereas, a party who owns a retail station has limited information collection requirements involving the retention of customary business records (*e.g.,* PTDs) or affixing labels.

This information collection will result in the replacement of the following existing and approved information collections under part 80: 2060–0178 (Reid Vapor Pressure), 2060–0275 (Detergent Additives), 2060–0277 (Reformulated Gasoline and Anti-Dumping), 2060–0308 (Diesel Sulfur), 2060–0692 (Performance-Based Test Methods), 2060–0675 (E15), and 2060–0437 (''Tier 3'') Gasoline Sulfur. These collections currently total $64,375,590. This collection totals $53,704,290, which represents a cost savings of $10,671,300.

Respondents/affected entities: The respondents to this information collection are parties involved in the 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 40 CFR part 1090.

Estimated number of respondents: 134,668.

Frequency of response: Annual, quarterly, and occasionally.

Total estimated burden: 608,992 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $53,704,290 (per year), of which $36,787,434 represents capital/overhead and maintenance cost ($5,744,016) and purchased services ($31,043,418). The estimated labor costs are $19,722,363.

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. When OMB approves this ICR, EPA will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this 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 consolidates EPA's existing fuel quality regulations into the new 40 CFR part 1090, and the 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 changes.

To the contrary, we have quantified overall cost savings from this action.[150] Even in those areas where we are imposing provisions with new costs for some entities, they are either offset by other larger cost savings or far below having any significant economic impact on a substantial number of small entities. 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. EPA believes, however, that this rule may be of significant interest to state and local governments. To the extent that states have adopted fuel regulations based on EPA's regulatory provisions that we are changing, they may need to make corresponding changes to their regulations to maintain their effectiveness. Consistent with the EPA's policy to promote communications between EPA and state and local governments, EPA consulted with representatives of various state and local governments early in the process of developing this rule to permit them to have meaningful and timely input into its development. 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).

[150] See Section XIV.C.

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 action 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 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 consolidates 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 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 action involves technical standards. EPA is updating 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, EPA is incorporating 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.

EPA continues to reference the following standards, previously approved for incorporation by reference, without change in part 1065: ASTM D86–12, D93–13, D445–12, D613–13, D4052–11, D5186–03 (R2009).

This rulemaking involves environmental monitoring or measurement. Consistent with EPA's Performance Based Measurement System (PBMS), for those fuel parameters that fall under PBMS (*e.g.,* sulfur, benzene, Reid Vapor Pressure, and oxygenate content), EPA has decided not to require the use of specific, prescribed analytic methods. Rather, EPA will 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. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the performance criteria specified. EPA will also allow 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.

TABLE XV.J–1—STANDARDS AND TEST METHODS TO BE INCORPORATED BY REFERENCE

Organization and standard or test method	Description
American Institute of Certified Public Accountants—AICPA Code of Professional Conduct, updated through June 2020.	Document describes principles to establish a code of professional conduct for external auditors.
American Institute of Certified Public Accountants—Statements on Quality Control Standards (SQCS) No. 8, QC Section 10: A Firm's System of Quality Control, current as of 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.
American Institute of Certified Public Accountants—Statement on Standards for Attestation Engagements No. 18, Attestation Standards: Clarification and Recodification, Issued April 2016.	Document describes standard practices for external auditors to perform attestation engagements using agreed-upon procedures.
ASTM D86–20a, Standard Test Method for Distillation of Petroleum Products and Liquid Fuels at Atmospheric Pressure, approved July 1, 2020.	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 D975–20a, Standard Specification for Diesel Fuel, approved June 1, 2020.	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 D3606–20e1, Standard Test Method for Determination of Benzene and Toluene in Spark Ignition Fuels by Gas Chromatography, approved July 1, 2020.	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.
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 D4806–20, Standard Specification for Denatured Fuel Ethanol for Blending with Gasolines for Use as Automotive Spark-Ignition Engine Fuel, approved May 1, 2020.	Specification describes the characteristic values for several parameters to be considered suitable as denatured fuel ethanol for blending with gasoline.
ASTM D4814–20a, Standard Specification for Automotive Spark-Ignition Engine Fuel, approved April 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 D5186–20, Standard Test Method for Determination of the Aromatic Content and Polynuclear Aromatic Content of Diesel Fuels By Supercritical Fluid Chromatography, approved July 1, 2020.	Test method describes how to determine the aromatic content in diesel fuel.
ASTM D5191–20, Standard Test Method for Vapor Pressure of Petroleum Products and Liquid Fuels (Mini Method), approved May 1, 2020.	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.

TABLE XV.J–1—STANDARDS AND TEST METHODS TO BE INCORPORATED BY REFERENCE—Continued

Organization and standard or test method	Description
ASTM D5500–20a, Standard Test Method for Vehicle Evaluation of Unleaded Automotive Spark-Ignition Engine Fuel for Intake Deposit Formation, approved June 1, 2020.	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 D5769–20, Standard Test Method for Determination of Benzene, Toluene, and Total Aromatics in Finished Gasolines by Gas Chromatography/Mass Spectrometry, approved June 1, 2020.	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 D6299–20, Standard Practice for Applying Statistical Quality Assurance and Control Charting Techniques to Evaluate Analytical Measurement System Performance, approved May 1, 2020.	Document establishes procedures to evaluate measurement system performance relative to statistical criteria for ensuring reliable measurements.
ASTM D6550–20, Standard Test Method for Determination of Olefin Content of Gasolines by Supercritical-Fluid Chromatography, approved July 1, 2020.	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 D6729–14, Standard Test Method for Determination of Individual Components in Spark Ignition Engine Fuels by 100 Metre Capillary High Resolution Gas Chromatography, approved October 1, 2014.	Test method describes how to determine the benzene content of butane and pentane.
ASTM D6730–19, Standard Test Method for Determination of Individual Components in Spark Ignition Engine Fuels by 100-Metre Capillary (with Precolumn) High-Resolution Gas Chromatography, approved July 1, 2019.	Test method describes how to determine the benzene content of butane and pentane.
ASTM D6751–20, Standard Specification for Biodiesel Fuel Blend Stock (B100) for Middle Distillate Fuels, approved January 1, 2020.	Document establishes specifications for neat biodiesel to be blended into diesel fuel.
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 (Reapproved 2020), 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 May 1, 2020.	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.
ASTM D7777–13 (Reapproved 2018)e1, Standard Test Method for Density, Relative Density, or API Gravity of Liquid Petroleum by Portable Digital Density Meter, approved October 1, 2018.	Test method describes how to measure the density of fuels and other petroleum products, expressed in terms of API gravity.
CARB Test Method, 13 CA ADC § 2257; California Code of Regulations Title 13. Motor Vehicles, Division 3. Air Resources Board, Chapter 5. Standards for Motor Vehicle Fuels, Article 1. Standards for Gasoline, Subarticle 1. Gasoline Standards that Became Applicable Before 1996, § 2257. Required Additives in Gasoline; amendment filed May 17, 1999.	Test method describes a vehicle test procedure to evaluate intake valve deposit formation of gasoline.
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.
NIST Handbook 158, Field Sampling Procedures for Fuel and Motor Oil Quality Testing—A Handbook for Use by Fuel and Oil Quality Regulatory Officials, 2016 Edition, April 2016.	Document describes procedures for drawing fuel samples from blender pumps and other in-field installations for testing to measure fuel parameters.

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 action 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.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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 as well as Public Law 109–58. Additional support for the procedural and compliance related aspects of this action 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 Parts 60, 63, 1042, and 1043

Administrative practice and procedure, Air pollution control.

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 1065

Administrative practice and procedure, Air pollution control, Incorporation by reference.

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.

Dated: October 15, 2020.

Andrew Wheeler,

Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR parts 60, 63, 79, 80, 1042, 1043, and 1065 and adds 40 CFR part 1090 as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

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

Subpart IIII—Standards of Performance for Stationary Compression Ignition Internal Combustion Engines

■ 2. Amend § 60.4207 by:

■ a. Removing and reserving paragraph (a);

■ b. In paragraph (b), removing ''40 CFR 80.510(b)'' and adding ''40 CFR 1090.305'' in its place; and

■ c. Revising paragraph (d).

The revision reads as follows:

§ 60.4207 What fuel requirements must I meet if I am an owner or operator of a stationary CI internal combustion engine subject to this subpart?

* * * * *

(d) Beginning June 1, 2012, owners and operators of stationary CI ICE subject to this subpart with a displacement of greater than or equal to 30 liters per cylinder must use diesel fuel that meets a maximum per-gallon sulfur content of 1,000 parts per million (ppm).

* * * * *

Subpart JJJJ—Standards of Performance for Stationary Spark Ignition Internal Combustion Engines

§ 60.4235 [Amended]

■ 3. Amend § 60.4235 by removing ''40 CFR 80.195'' and adding ''40 CFR 1090.205'' in its place.

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 4. The authority citation for part 63 continues to read as follows:

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

Subpart R—National Emission Standards for Gasoline Distribution Facilities (Bulk Gasoline Terminals and Pipeline Breakout Stations)

■ 5. Amend § 63.421 by revising the definitions for ''Oxygenated gasoline'' and ''Reformulated gasoline'' to read as follows:

§ 63.421 Definitions.

* * * * *

Oxygenated gasoline means the same as defined in 40 CFR 80.2.

* * * * *

Reformulated gasoline means the same as defined in 40 CFR 80.2.

* * * * *

Subpart ZZZZ—National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines

§ 63.6604 [Amended]

■ 6. In § 63.6604, amend paragraphs (a), (b), and (c) by removing ''40 CFR 80.510(b)'' and adding ''40 CFR 1090.305'' in its place.

PART 79—REGISTRATION OF FUEL AND FUEL ADDITIVES

■ 7. 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

■ 8. 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 fuel in subpart D of this part, or the later registration of a fuel 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

■ 9. 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 1090.260.

* * * * *

(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 1090.260.

(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) *Nomenclature.* 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) *Designation.* 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 1090.260. 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 1090.260.

(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 1090.260.

(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.

■ 10. 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 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 1090.260.

Subpart D—Designation of Fuels and Additives

■ 11. 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.

* * * * *

■ 12. Amend § 79.33 by revising paragraph (c) to read as follows:

§ 79.33 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

■ 13. 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

■ 14. 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.

■ 15. 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 (C3) 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) (42 U.S.C. 7545(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) (42 U.S.C. 7545(m)(2)).

Conventional gasoline or CG means any gasoline that has been certified under 40 CFR 1090.1000(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 (2) of this definition.

(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.

[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.

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.

Locomotive engine means an engine used in a locomotive as defined under 40 CFR 92.2.

Marine engine has the meaning given in 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 (42 U.S.C. 7545(f)(1)), or be permitted under a waiver granted by the Administrator under the authority of section 211(f)(4) of the Clean Air Act (42 U.S.C. 7545(f)(4)).

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 40 CFR 1090.1000(b), and which meets each of the standards and requirements prescribed under 40 CFR 1090.220.

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]

■ 16. Effective January 1, 2022, remove and reserve § 80.3.

§ 80.7 [Amended]

■ 17. In § 80.7, amend paragraph (c) by removing ''§ 80.22'' and adding ''40 CFR 1090.1550'' in its place.

Subpart B—Controls and Prohibitions

§ § 80.22, 80.23, and 80.26 through 80.33 [Removed and reserved]

■ 18. Effective January 1, 2022, remove and reserve §§ 80.22, 80.23, and 80.26 through 80.33.

Subparts D, E, F, G, H, I, J, K, L, N, and O and Appendices A and B to Part 80—[Removed and reserved]

■ 19. Effective January 1, 2022, remove and reserve subparts D through L, N, and O and appendices A and B to Part 80.

Subpart M—Renewable Fuel Standard

§ 80.1400 [Amended]

■ 20. Amend § 80.1400 by removing the second sentence of the introductory text.

■ 21. Amend § 80.1401 by:

■ a. Revising the definition of ''Certified non-transportation 15 ppm distillate fuel'';

■ b. In paragraph (2) in the definition of ''Fuel for use in an ocean-going vessel'', removing ''§§ 80.2(ttt) and 80.510(k)'' and adding ''§ 80.2 and 40 CFR 1090.80'' in its place;

■ c. In paragraph (1) in the definition of ''Heating oil'', removing ''§ 80.2(ccc)'' and adding ''§ 80.2'' in its place;

■ d. In the definition of ''Renewable gasoline'', removing ''§ 80.2(c)'' and adding ''§ 80.2'' in its place; and

■ e. In the definition of ''Renewable gasoline blendstock'', removing ''§ 80.2(s)'' and adding ''§ 80.2'' in its place. The revision reads as follows:

§ 80.1401 Definitions.

* * * * *

Certified non-transportation 15 ppm distillate fuel or *certified NTDF* means distillate fuel that meets all the following:

(1) The fuel has been certified under 40 CFR 1090.1000 as meeting the ULSD standards in 40 CFR 1090.305.

(2) The fuel has been designated under 40 CFR 1090.1015 as certified NTDF.

(3) The fuel has also been designated under 40 CFR 1090.1015 as 15 ppm heating oil, 15 ppm ECA marine fuel, or other non-transportation fuel (*e.g.,* jet fuel, kerosene, or distillate global marine fuel).

(4) The fuel has not been designated under 40 CFR 1090.1015 as ULSD or 15 ppm MVNRLM diesel fuel.

(5) The PTD for the fuel meets the requirements in § 80.1453(e).

* * * * *

■ 22. Amend § 80.1407 by:

■ a. In paragraph (e), removing ''§ 80.2(qqq)'' and adding ''§ 80.2'' in its place; and

■ b. Revising paragraph (f)(7).

The revision reads 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 1090.500.

* * * * *

§ 80.1416 [Amended]

■ 23. In § 80.1416, amend paragraph (b)(1)(i) by removing ''§ 80.76'' and adding ''40 CFR 1090.805'' in its place.

§ 80.1427 [Amended]

■ 24. Amend § 80.1427 by:

■ a. In paragraph (a)(2) introductory text, removing ''Except as described in paragraph (a)(4) of this section,''; and

■ b. Removing and reserving paragraph (a)(4).

§ 80.1429 [Amended]

■ 25. Amend § 80.1429 by:

■ a. In paragraph (b)(9) introductory text, removing ''RBOB, or CBOB'' and adding ''or BOB'' in its place; and

■ b. Removing paragraphs (f) and (g).

§ 80.1440 [Amended]

■ 26. In § 80.1440, amend paragraph (a)(2) by removing ''any other subpart of 40 CFR part 80 (*e.g.,* §§ 80.606, 80.1655)'' and adding ''40 CFR 1090.605'' in its place.

§ 80.1441 [Amended]

■ 27. Amend § 80.1441 by removing paragraphs (a)(6) and (b)(4).

§ 80.1442 [Amended]

■ 28. Amend § 80.1442 by removing paragraphs (a)(3) and (b)(6).

§ 80.1450 [Amended]

■ 29. Amend § 80.1450 by:

■ a. In paragraphs (a), (b) introductory text, and (c), removing ''§ 80.76'' and adding ''40 CFR 1090.805'' in its place;

■ b. In paragraph (d)(3)(iii), removing ''§ 80.127'' and adding ''40 CFR 1090.1805'' in its place; and

■ c. In paragraphs (e) and (g)(1), removing ''§ 80.76'' and adding ''40 CFR 1090.805'' in its place.

§ 80.1453 [Amended]

■ 30. In § 80.1453, amend paragraph (e)(1) by removing ''§ 80.590'' and adding ''40 CFR 1090.1115'' in its place.

§ 80.1454 [Amended]

■ 31. In § 80.1454, amend paragraph (h)(2)(i) by removing ''§ 80.68(c)(13)(i)'' and adding ''40 CFR 1090.55'' in its place.

§ 80.1464 [Amended]

■ 32. Amend § 80.1464 by:

■ a. In the introductory text, removing ''§§ 80.125 through 80.127, and 80.130,'' and adding ''40 CFR 1090.1800'' in its place;

■ b. In paragraph (a)(1)(iii), removing ''§ 80.133'' and adding ''40 CFR 1090.1810'' in its place; and

■ c. In paragraphs (a)(1)(iv)(D), (a)(2)(i), (b)(1)(iv), (b)(1)(v)(A), (b)(2)(i), and (c)(1)(i), removing ''§ 80.127'' and adding ''40 CFR 1090.1805'' in its place.

§ 80.1465 [Removed and reserved]

■ 33. Remove and reserve § 80.1465.

§ 80.1466 [Amended]

■ 34. Amend § 80.1466 by:

■ a. In paragraph (d)(3)(ii), removing ''§ 80.65(f)(2)(iii)'' and adding ''40 CFR 1090.1805'' in its place;

■ b. In paragraphs (m)(3) introductory text, (m)(4) introductory text, and (m)(5), removing ''§ 80.127'' and adding ''40 CFR 1090.1805'' in its place; and

■ c. In paragraphs (m)(6)(ii) and (iii), removing ''§§ 80.125 through 80.127, 80.130'' and adding ''40 CFR 1090.1800'' in its place.

§ 80.1467 [Amended]

■ 35. In § 80.1467, amend paragraphs (h)(2) and (3) by removing ''§§ 80.125 through 80.127, 80.130,'' and adding ''40 CFR 1090.1800'' in its place.

* * * * *

§ 80.1469 [Amended]

■ 36. In § 80.1469, amend paragraph (c)(5) by removing ''§ 80.127'' and adding ''40 CFR 1090.1805'' in its place.

§ 80.1475 [Amended]

■ 37. In § 80.1475, amend paragraph (d)(4)(ii) by removing ''§ 80.590'' and adding ''40 CFR 1090.1115'' in its place.

PART 1042—CONTROL OF EMISSIONS FROM NEW AND IN-USE MARINE COMPRESSION-IGNITION ENGINES AND VESSELS

■ 38. The authority citation for part 1042 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart G—Special Compliance Provisions

§ 1042.660 [Amended]

■ 39. In § 1042.660, amend paragraph (a) by removing ''40 CFR part 80'' and adding ''40 CFR part 1090'' in its place.

Subpart J—Definitions and Other Reference Information

§ 1042.901 [Amended]

■ 40. In § 1042.901, amend the definition of ''Diesel fuel'' by removing ''40 CFR 80.2'' and adding ''40 CFR 1090.80'' in its place.

PART 1043— CONTROL OF NO_X, SO_X, AND PM EMISSIONS FROM MARINE ENGINES AND VESSELS SUBJECT TO THE MARPOL PROTOCOL

■ 41. The authority citation for part 1043 continues to read as follows:

Authority: 33 U.S.C. 1901–1912.

§ 1043.1 [Amended]

■ 42. In § 1043.1, amend paragraph (f) by removing ''40 CFR part 80'' and adding ''40 CFR part 1090'' in its place.

§ 1043.60 [Amended]

■ 43. In § 1043.60, amend paragraphs (d) and (e) by removing ''40 CFR part 80'' and adding ''40 CFR part 1090'' in its place.

§ 1043.70 [Amended]

■ 44. In § 1043.70, amend paragraphs (c) and (d) by removing ''40 CFR part 80'' and adding ''40 CFR part 1090'' in its place.

§ 1043.80 [Amended]

■ 45. In § 1043.80, amend paragraph (b)(5) by removing ''40 CFR part 80'' and adding ''40 CFR part 1090'' in its place.

PART 1065—ENGINE-TESTING PROCEDURES

■ 46. The authority citation for part 1065 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart H—Engine Fluids, Test Fuels, Analytical Gases and Other Calibration Standards

■ 47. Amend § 1065.701 by revising paragraph (d)(2) to read as follows:

§ 1065.701 General requirements for test fuels.

* * * * *

(d) * * *

(2) The fuel parameters specified in this subpart depend on measurement procedures that are incorporated by reference. For any of these procedures, you may instead rely upon the procedures identified in 40 CFR part 1090 for measuring the same parameter. For example, we may identify different reference procedures for measuring gasoline parameters in 40 CFR 1090.1360.

* * * * *

■ 48. Effective December 4, 2020, amend § 1065.703 by revising Table 1 of § 1065.703 to read as follows:

§ 1065.703 Distillate diesel fuel.

* * * * *

TABLE 1 OF § 1065.703—TEST FUEL SPECIFICATIONS FOR DISTILLATE DIESEL FUEL

Property	Unit	Ultra low sulfur	Low sulfur	High sulfur	Reference procedure [a]
Cetane Number	.....	40–50	40–50	40–50	ASTM D613
Distillation range:					
Initial boiling point	°C	171–204	171–204	171–204	ASTM D86
10 pct. point		204–238	204–238	204–238	
50 pct. point		243–282	243–282	243–282	
90 pct. point		293–332	293–332	293–332	
Endpoint		321–366	321–366	321–366	
Gravity	°API	32–37	32–37	32–37	ASTM D4052
Total sulfur	mg/kg	7–15	300–500	800–2500	ASTM D2622, ASTM D5453, or ASTM D7039
Aromatics, min. (Remainder shall be paraffins, naphthenes, and olefins).	g/kg	100	100	100	ASTM D5186
Flashpoint, min.	°C	54	54	54	ASTM D93
Kinematic Viscosity	mm^2/s	2.0–3.2	2.0–3.2	2.0–3.2	ASTM D445

[a] Incorporated by reference, see § 1065.1010. See § 1065.701(d) for other allowed procedures.

* * * * *

§ 1065.705 [Amended]

■ 49. In § 1065.705, amend the introductory text by removing ''40 CFR 80.2'' and adding ''40 CFR 1090.80'' in its place.

§ 1065.725 [Amended]

■ 50. In § 1065.725, amend paragraph (c) by removing ''denatured ethanol meeting the specifications in 40 CFR 80.1610'' and adding ''denatured fuel ethanol meeting the specifications in 40 CFR 1090.270'' in its place.

Subpart K—Definitions and Other Reference Information

■ 51. Effective December 4, 2020, amend § 1065.1010 by revising the last sentence of paragraph (a) and paragraphs (b)(19), (35), and (46) to read as follows:

§ 1065.1010 Incorporation by reference.

(a) * * * 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) * * *

(19) 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 §§ 1065.703(b) and 1065.710(b) and (c).

* * * * *

(35) 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 §§ 1065.703(b) and 1065.710(b).

* * * * *

(46) ASTM D7039–15a (Reapproved 2020), 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 May 1, 2020 (''ASTM D7039''), IBR approved for §§ 1065.703(b) and 1065.710(b).

* * * * *

■ 52. Effective December 4, 2020, add part 1090 to read as follows:

PART 1090—REGULATION OF FUELS, FUEL ADDITIVES, AND REGULATED BLENDSTOCKS

Subpart A—General Provisions

Sec.

Subpart B—General Requirements and Provisions for Regulated Parties

Subpart C—Gasoline Standards

Subpart D—Diesel Fuel and ECA Marine Fuel Standards

Subpart E—Reserved

Subpart F—Transmix and Pipeline Interface Provisions

Subpart G—Exemptions, Hardships, and Special Provisions

Subpart H—Averaging, Banking, and Trading Provisions

Subpart I—Registration

Subpart J—Reporting

Subpart K—Batch Certification and Designation

Subpart L—Product Transfer Documents

Subpart M—Recordkeeping

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 introduced into commerce 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. A party that produces and distributes 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 sulfur content for fuel used in marine vessels, including separate standards for marine 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. A party 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. A party 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) 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 for gasoline as specified in paragraph (b)(8) of this section), any approval granted under 40 CFR part 80 continues to be in effect under this part. For example, if EPA approved the use of an alternative label 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, a regulated party 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.

(6) A party may comply with the PTD requirements of 40 CFR part 80 instead of the requirements of subpart L of this part until May 1, 2021.

(7) A party may comply with the automatic sampling provisions of 40 CFR 80.8 instead of the requirements in § 1090.1335(c) until January 1, 2022.

(8) A gasoline manufacturer may operate under an in-line blending waiver issued under 40 CFR part 80 until January 1, 2022, or until EPA approves a revised in-line blending waiver under § 1090.1315, whichever is earlier. The following provisions apply:

(i) A gasoline manufacturer operating under an in-line blending waiver under 40 CFR 80.65 must monitor and test for sulfur content, benzene content, and for summer gasoline, RVP, and may discontinue monitoring and testing for other properties that are included in their in-line blending waiver.

(ii) The auditing requirements in § 1090.1850 do not apply to an in-line blending waiver issued under 40 CFR part 80.

(c) The following requirements apply for the 2021 compliance period:

(1) The NSTOP specified in § 1090.1450 must begin no later than June 1, 2021.

(2) A gasoline manufacturer that accounts for oxygenate added downstream under § 1090.710 is deemed compliant with the requirement to participate in the NSTOP specified in § 1090.710(a)(3) until June 1, 2021, if the gasoline manufacturer meets all other applicable requirements specified in § 1090.710.

(3) The independent surveyor conducting the NSTOP must submit the proof of contract required under § 1090.1400(b) no later than April 15, 2021.

(4) The independent surveyor may collect only one summer or winter gasoline sample for each participating fuel manufacturing facility instead of the minimum two samples required under § 1090.1450(c)(2)(i).

§ 1090.10 Contacting EPA.

A party 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 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, if applicable.

(3) The general nature of a request.

(4) The relevant time period for a 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, if applicable.

(3) The general nature of a request.

(4) The relevant time period for a request, if applicable.

(5) The extent to which EPA either granted or denied the request and any relevant terms and 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 may impose terms and conditions on any approval of any submission required or allowed under this part.

(c) EPA will deny any request for approval if the submission is incomplete, contains inaccurate or misleading information, or does not meet all specified requirements.

(d) 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.

(e) 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.

(f) 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) 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.

(b) Do not round intermediate values to transfer data unless the rounded number has at least 6 significant digits.

(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 N 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 11,000 gallons to the nearest 10 gallons.

(ii) Round batch volumes above 11,000 gallons to the nearest 100 gallons.

§ 1090.55 Requirements for independent parties.

This section specifies how a third party demonstrates 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 each person involved in the specified activities in this part that the independent third party is hired to perform for a regulated party, except that an internal auditor may instead meet the requirements in § 1090.1800(b)(1)(i).

(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 12 months 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.

(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) An independent surveyor that conducts a survey under subpart O of this part must have personnel familiar with petroleum marketing, the sampling and testing of gasoline and diesel fuel at retail stations, and the designing of surveys to estimate compliance rates for fuel parameters nationwide. The independent surveyor must demonstrate this technical ability in plans submitted under subpart O of this part.

(2) A laboratory 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. The independent third party must demonstrate work experience and a good working knowledge of the VCSB methods 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) Any person auditing in-line blending operations must demonstrate work experience and be proficient in the VCSB methods 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 that is produced by a transmix processor under § 1090.515.

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 in order 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 S 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. This also includes fuel, fuel additive, or regulated blendstock for which homogeneity testing is not required under § 1090.1337(a).

Biodiesel means a diesel fuel composed of mono-alkyl esters made from nonpetroleum feedstocks.

Blender pump means any fuel dispenser where PCG is blended with E85 (made only with PCG and DFE) or DFE to produce gasoline that has an ethanol content greater than that of the PCG. A fuel dispenser that produces gasoline with anything other than PCG and DFE (*e.g.,* natural gas liquids) is a fuel blending facility.

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) that meets 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) that meets 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) that meets the definition of ''Category 3'' in 40 CFR part 1042.901.

CBOB means a BOB produced or imported for use outside of an RFG covered area.

Certified butane means butane that is certified to meet the requirements in § 1090.250.

Certified butane blender means a blending manufacturer that produces gasoline by blending certified butane into PCG and that uses the provisions of § 1090.1320(b) to meet the applicable sampling and testing requirements.

Certified butane producer means a regulated blendstock producer that certifies butane as meeting the requirements in § 1090.250.

Certified ethanol denaturant means ethanol denaturant that is certified to meet the requirements in § 1090.275.

Certified ethanol denaturant producer means any person that certifies ethanol denaturant as meeting the requirements in § 1090.275.

Certified non-transportation 15 ppm distillate fuel or *certified NTDF* has the meaning given in 40 CFR 80.1401.

Certified pentane means pentane that is certified to meet the requirements in § 1090.255.

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 § 1090.255.

Compliance period means the calendar year (January 1 through December 31).

Conventional gasoline (CG) means gasoline that is not certified to meet the requirements for RFG in § 1090.220.

Crosscheck program means 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 accuracy of individual laboratories and measurement systems.

Days means calendar days, including weekends and holidays.

Denatured fuel ethanol (DFE) means anhydrous ethanol that contains a denaturant to make it unfit for human consumption, that is produced or imported for use in gasoline, and that meets the standards and requirements in § 1090.270.

Detergent means any chemical compound or combination of chemical compounds that is added to gasoline to control deposit formation and meets the requirements in § 1090.260. 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. A detergent manufacturer is a fuel additive manufacturer.

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 or a fuel blend that contains NP diesel fuel) that is intended or used to power a vehicle or engine that is designed to operate using diesel 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 that owns, leases, operates, controls, or supervises a fuel manufacturing facility where diesel fuel is produced or imported.

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. T90 temperature is based on the distillation test method specified in § 1090.1350.

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 fuel manufacturing facility gate at which it was certified (*e.g.,* fuel at facilities of distributors, pipelines, terminals, carriers, retailers, oxygenate blenders, and WPCs).

E0 means 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. E85 is not gasoline.

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 ECA, or an ECA associated area.

Ethanol means an alcohol of the chemical formula C_2H_5OH.

Ethanol denaturant means PCG, gasoline blendstocks, or natural gas 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.

Fuel additive means has the same meaning as *additive* in 40 CFR 79.2(e).

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 the fuel manufacturer certified the fuel.

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.

(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 (BOB) means gasoline for which a gasoline manufacturer has accounted for oxygenate added downstream under § 1090.710. 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 that owns, leases, operates, controls, or supervises a fuel manufacturing facility where gasoline is produced, imported, or recertified.

Gasoline regulated blendstock means a regulated blendstock that is used or intended for use as a component of gasoline.

Gasoline treated as blendstock (GTAB) means a gasoline regulated blendstock that is imported and used to produce gasoline as specified in § 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. (Note: This part regulates global marine fuel only if it qualifies as a distillate fuel.)

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 O of this part.

Intake valve deposits (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 (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 (NGLs) means natural gasoline or other mixtures of hydrocarbons (primarily but not limited to 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 renewable fuel under 40 CFR part 80, subpart M, that is used or intended for use to power a vehicle or engine that is designed to operate using diesel fuel or that is made available for use in a vehicle or engine designed to operate using diesel fuel.

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 a 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 (PCG) means CG, RFG, or BOB that has been certified as a batch by a gasoline manufacturer.

Product transfer documents (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 a BOB produced or imported for use in an RFG covered area.

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 (RFG) means gasoline that is certified under § 1090.1000(b) and that meets each of the standards and requirements in § 1090.220.

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 a retailer or WPC, 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. For example, No. 5 fuels and No. 6 fuels are residual fuels. Residual fuel grades are specified in ASTM D396 and ISO 8217. T90 temperature is based on the distillation test method specified in § 1090.1350.

Responsible corporate officer (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 fuel 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 § 1090.285 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 § 1090.285.

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 (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 if it 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 of gasoline and distillate fuel 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 under § 1090.500.

Transmix distillate product (TDP) means the diesel fuel blendstock that is produced when transmix is separated into blendstocks at a transmix processing facility.

Transmix gasoline product (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. A transmix processor is a fuel manufacturer.

Ultra low-sulfur diesel (ULSD) means diesel fuel that is certified to meet the standards 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 the following:

(1) For an automated detergent blending facility, the VAR period is 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.

(2) For a non-automated detergent blending facility, the VAR Period constitutes the blending of one batch of gasoline.

Voluntary consensus standards body (VCSB) means 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.

Wholesale purchaser-consumer (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 duration 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 parties.

(a) *Types of provisions.* The term ''provision'' includes all aspects of the regulations in this part. As specified in this section, regulatory provisions include standards, requirements, and prohibitions, along with a variety of other types of provisions.

(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. 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 must not do. 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) *Subject to.* 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 exempt 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 are not exhaustive.

§ 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.

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.
NFSP	national fuels survey program.
NGL	natural gas liquids.
NIST	National Institute for Standards and Technology.
NSTOP	national sampling and testing oversight program.
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 distillate product.
TGP	transmix gasoline product.
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 also available from the sources listed in this section. This material 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, (888) 777–7077, or *www.aicpa.org.*

(1) AICPA Code of Professional Conduct, updated through June 2020; IBR approved for § 1090.1800(b).

(2) Statements on Quality Control Standards (SQCS) No. 8, QC Section 10: A Firm's System of Quality Control, current as of July 1, 2019; IBR approved for § 1090.1800(b).

(3) Statement on Standards for Attestation Engagements No. 18, Attestation Standards: Clarification and Recodification, Issued April 2016; 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 D86–20a, Standard Test Method for Distillation of Petroleum Products and Liquid Fuels at Atmospheric Pressure, approved July 1, 2020 (''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(d).

(3) ASTM D975–20a, Standard Specification for Diesel Fuel, approved June 1, 2020 (''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(d).

(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 D3606–20e1, Standard Test Method for Determination of Benzene and Toluene in Spark Ignition Fuels by Gas Chromatography, approved July 1, 2020 (''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(d).

(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(a) 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 D4806–20, Standard Specification for Denatured Fuel Ethanol for Blending with Gasolines for Use as Automotive Spark-Ignition Engine Fuel, approved May 1, 2020 (''ASTM D4806''); IBR approved for § 1090.1395(a).

(18) ASTM D4814–20a, Standard Specification for Automotive Spark-Ignition Engine Fuel, approved April 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 D5186–20, Standard Test Method for Determination of the Aromatic Content and Polynuclear Aromatic Content of Diesel Fuels By Supercritical Fluid Chromatography, approved July 1, 2020 (''ASTM D5186''); IBR approved for § 1090.1350(b).

(21) ASTM D5191–20, Standard Test Method for Vapor Pressure of Petroleum Products and Liquid Fuels (Mini Method), approved May 1, 2020 (''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 D5500–20a, Standard Test Method for Vehicle Evaluation of Unleaded Automotive Spark-Ignition Engine Fuel for Intake Deposit Formation, approved June 1, 2020 (''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 D5769–20, Standard Test Method for Determination of Benzene, Toluene, and Total Aromatics in Finished Gasolines by Gas Chromatography/Mass Spectrometry, approved June 1, 2020 (''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(a).

(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 D6299–20, Standard Practice for Applying Statistical Quality Assurance and Control Charting Techniques to Evaluate Analytical Measurement System Performance, approved May 1, 2020 (''ASTM D6299''); IBR approved for §§ 1090.1370(c), 1090.1375(a), (b), and (c), and 1090.1450(c).

(31) ASTM D6550–20, Standard Test Method for Determination of Olefin Content of Gasolines by Supercritical-Fluid Chromatography, approved July 1, 2020 (''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 §§ 1090.1360(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 D6729–14, Standard Test Method for Determination of Individual Components in Spark Ignition Engine Fuels by 100 Metre Capillary High Resolution Gas Chromatography, approved October 1, 2014 (''ASTM D6729''); IBR approved for § 1090.1350(b).

(35) ASTM D6730–19, Standard Test Method for Determination of Individual Components in Spark Ignition Engine Fuels by 100-Metre Capillary (with Precolumn) High-Resolution Gas Chromatography, approved July 1, 2019 (''ASTM D6730''); IBR approved for § 1090.1350(b).

(36) ASTM D6751–20, Standard Specification for Biodiesel Fuel Blend Stock (B100) for Middle Distillate Fuels, approved January 1, 2020 (''ASTM D6751''); IBR approved for § 1090.1350(b).

(37) 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 § 1090.1450(c).

(38) ASTM D7039–15a (Reapproved 2020), 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 May 1, 2020 (''ASTM D7039''); IBR approved for § 1090.1365(b).

(39) 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).

(40) ASTM D7777–13 (Reapproved 2018)e1, Standard Test Method for Density, Relative Density, or API Gravity of Liquid Petroleum by Portable Digital Density Meter, approved October 1, 2018 (''ASTM D7777''); IBR approved for § 1090.1337(d).

(d) Environmental Protection Agency, Air and Radiation Docket and Information Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460, (202) 566–1742.

(1) CARB Test Method, 13 CA ADC § 2257; California Code of Regulations Title 13. Motor Vehicles, Division 3. Air Resources Board, Chapter 5. Standards for Motor Vehicle Fuels, Article 1. Standards for Gasoline, Subarticle 1. Gasoline Standards that Became Applicable Before 1996, § 2257. Required Additives in Gasoline; amendment filed May 17, 1999.

(2) [Reserved]

(e) The Institute of Internal Auditors, 1035 Greenwood Blvd., Suite 401, Lake Mary, FL 32746, (407) 937–1111, or *www.theiia.org.*

(1) International Standards for the Professional Practice of Internal Auditing (Standards), Revised October 2016; IBR approved for § 1090.1800(b).

(2) [Reserved]

(f) 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, Field Sampling Procedures for Fuel and Motor Oil Quality Testing—A Handbook for Use by Fuel and Oil Quality Regulatory Officials, 2016 Edition, April 2016; IBR approved for § 1090.1410(b).

(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 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 that also transports fuel must meet the requirements applicable to a fuel manufacturer and a distributor. A regulated party is 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 M 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 R 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 of paragraphs (a) through (c) of this section and § 1090.105, an importer must also comply with subpart Q of this part.

§ 1090.105 Fuel manufacturers.

This section provides an overview of general requirements applicable to a fuel manufacturer. A gasoline manufacturer must comply with the requirements of paragraph (a) of this section. A diesel fuel or IMO marine fuel manufacturer must comply with the requirements of paragraph (b) of this section.

(a) *Gasoline manufacturers.* Except as specified otherwise in this subpart, a gasoline manufacturer must comply with the following requirements:

(1) *Producing compliant gasoline.* A gasoline manufacturer must produce or import gasoline that meets the standards of subpart C of this part and must comply with the ABT requirements in subpart H of this part.

(2) *Registration.* A gasoline manufacturer must register with EPA under subpart I of this part.

(3) *Reporting.* A gasoline manufacturer must submit reports to EPA under subpart J of this part.

(4) *Certification and designation.* A gasoline manufacturer must certify and designate the gasoline they produce under subpart K of this part.

(5) *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 L of this part.

(6) *Sampling, testing, and sample retention.* A gasoline manufacturer must conduct sampling, testing, and sample retention in accordance with subpart N of this part.

(7) *Surveys.* A gasoline manufacturer may participate in applicable fuel surveys under subpart O of this part.

(8) *Annual attest engagement.* A gasoline manufacturer must submit annual attest engagement reports to EPA under subpart S of this part.

(b) *Diesel fuel and IMO marine fuel manufacturers.* A diesel fuel or IMO marine fuel manufacturer must comply with the following requirements, as applicable:

(1) *Producing compliant diesel fuel and ECA marine fuel.* A diesel fuel or ECA marine fuel manufacturer must produce or import diesel fuel or ECA marine fuel that meets the requirements of subpart D of this part.

(2) *Registration.* A diesel fuel or ECA marine fuel manufacturer must register with EPA under subpart I of this part.

(3) *Reporting.* A diesel fuel manufacturer must submit reports to EPA under subpart J of this part.

(4) *Certification and designation.* A diesel fuel or ECA marine fuel manufacturer must certify and designate the diesel fuel or ECA marine fuel they produce under subpart K of this part. A distillate global marine fuel manufacturer must designate the distillate global marine fuel they produce under subpart K of this part.

(5) *PTDs.* On each occasion when a diesel fuel or IMO marine fuel manufacturer transfers custody or title to any diesel fuel or IMO marine fuel, the transferor must provide to the transferee PTDs under subpart L of this part.

(6) *Sampling, testing, and retention requirements.* A diesel fuel or ECA marine fuel manufacturer must conduct sampling, testing, and sample retention in accordance with subpart N of this part.

(7) *Surveys.* A diesel fuel manufacturer may participate in applicable fuel surveys under subpart O of this part.

(8) *Distillate global marine fuel manufacturers.* A distillate global marine fuel manufacturer does not need to comply with the requirements of paragraphs (b)(1) through (3), and (6) of this section for global marine fuel that is exempt from the standards in subpart D of this part, as specified in § 1090.650.

§ 1090.110 Detergent blenders.

A detergent blender must comply with the requirements of this section.

(a) *Gasoline standards.* A detergent blender 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 L of this part.

(c) *Recordkeeping.* A detergent blender must demonstrate compliance with the requirements in § 1090.260(a) as specified in § 1090.1240.

(d) *Equipment calibration.* A detergent blender at an automated

detergent blending facility must calibrate their detergent blending equipment in accordance with subpart N of this part.

§ 1090.115 Oxygenate blenders.

An oxygenate blender must comply with the requirements of this section.

(a) *Gasoline standards.* An oxygenate blender must comply with the applicable requirements of subpart C of this part.

(b) *Registration.* An oxygenate blender 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 L of this part.

(d) *Oxygenate blending requirements.* An oxygenate blender must follow the blending instructions specified by the gasoline manufacturer under § 1090.710(a)(5) unless the oxygenate blender recertifies BOBs under § 1090.740.

§ 1090.120 Oxygenate producers.

This section provides an overview of general requirements applicable to an oxygenate producer (*e.g.,* a DFE or isobutanol producer). A DFE producer must comply with the requirements for an oxygenate producer in paragraph (a) of this section and the additional requirements specified in paragraph (b) of this section.

(a) *Oxygenate producers.* An oxygenate producer must comply with the following requirements:

(1) *Gasoline standards.* An oxygenate producer must comply with the applicable requirements of subpart C of this part.

(2) *Registration.* An oxygenate producer must register with EPA under subpart I of this part.

(3) *Reporting.* An oxygenate producer must submit reports to EPA under subpart J of this part.

(4) *Certification and designation.* An oxygenate producer must certify and designate the oxygenate they produce under subpart K of this part.

(5) *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 L of this part.

(6) *Sampling, testing, and retention requirements.* An oxygenate producer must conduct sampling, testing, and sample retention in accordance with subpart N of this part.

(b) *DFE producers.* In addition to the requirements specified in paragraph (a) of this section, a DFE producer must meet all the following requirements:

(1) Use denaturant that complies with the requirements specified in §§ 1090.270(b) and 1090.275.

(2) Participate in a survey program conducted by an independent surveyor under subpart O of this part if the DFE producer produces DFE made available for use in the production of E15.

§ 1090.125 Certified butane producers.

A certified butane producer must comply with the requirements of this section.

(a) *Gasoline standards.* A certified butane producer must comply with the applicable requirements of subpart C of this part.

(b) *Certification and designation.* A certified butane producer must certify and designate the certified butane they produce under subpart K of this part.

(c) *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 L of this part.

(d) *Sampling, testing, and retention requirements.* A certified butane producer must conduct sampling, testing, and sample retention in accordance with subpart N of this part.

§ 1090.130 Certified butane blenders.

A certified butane blender that blends certified butane into PCG is a gasoline manufacturer that may comply with the requirements of this section in lieu of the requirements in § 1090.105.

(a) *Gasoline standards.* A certified butane blender must comply with the applicable requirements of subpart C of this part.

(b) *Registration.* A certified butane blender must register with EPA under subpart I of this part.

(c) *Reporting.* A certified butane blender must submit reports to EPA under subpart J of this part.

(d) *PTDs.* When certified butane is blended with PCG, PTDs that accompany the gasoline blended with certified butane must comply with subpart L of this part.

(e) *Sampling and testing requirements.* A certified butane blender must comply with the alternative sampling and testing approach in § 1090.1320(b).

(f) *Survey.* A certified butane blender may participate in the applicable fuel surveys of subpart O of this part.

(g) *Annual attest engagement.* A certified butane blender must submit annual attest engagement reports to EPA under subpart S of this part.

§ 1090.135 Certified pentane producers.

A certified pentane producer must comply with the requirements of this section.

(a) *Gasoline standards.* A certified pentane producer must comply with the applicable requirements of subpart C of this part.

(b) *Registration.* A certified pentane producer must register with EPA under subpart I of this part.

(c) *Reporting.* A certified pentane producer must submit reports to EPA under subpart J of this part.

(d) *Certification and designation.* A certified pentane producer must certify and designate the certified pentane they produce under subpart K of this part.

(e) *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 L of this part.

(f) *Sampling, testing, and retention requirements.* A certified pentane producer must conduct sampling, testing, and sample retention in accordance with subpart N of this part.

§ 1090.140 Certified pentane blenders.

A certified pentane blender that blends certified pentane into PCG is a gasoline manufacturer that may comply with the requirements of this section in lieu of the requirements in § 1090.105.

(a) *Gasoline standards.* A certified pentane blender must comply with the applicable requirements of subpart C of this part.

(b) *Registration.* A certified pentane blender must register with EPA under subpart I of this part.

(c) *Reporting.* A certified pentane blender must submit reports to EPA under subpart J of this part.

(d) *PTDs.* When certified pentane is blended with PCG, PTDs that accompany the gasoline blended with pentane must comply with subpart L of this part.

(e) *Sampling, testing, and retention requirements.* A certified pentane blender must comply with the alternative sampling and testing approach in § 1090.1320(b).

(f) *Survey.* A certified pentane blender may participate in the applicable fuel surveys of subpart O of this part.

(g) *Annual attest engagement.* A certified pentane blender must submit annual attest engagement reports to EPA under subpart S of this part.

§ 1090.145 Transmix processors.

A transmix processor must comply with the requirements of this section.

(a) *Transmix requirements.* A transmix processor must comply with

the transmix requirements of subpart F of this part.

(b) *Registration.* A transmix processor must register with EPA under subpart I of this part.

(c) *Certification and designation.* A transmix processor must certify and designate the fuel they produce under subpart K of this part.

(d) *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 L of this part.

(e) *Sampling, testing, and retention requirements.* A transmix processor must conduct sampling, testing, and sample retention in accordance with subparts F and N of this part.

(f) *Reporting.* A transmix processor must submit reports to EPA under subpart J of this part.

(g) *Annual attest engagement.* A transmix processor must submit annual attest engagement reports to EPA under subpart S of this part.

§ 1090.150 Transmix blenders.

A transmix blender must comply with the requirements of this section.

(a) *Transmix requirements.* A transmix blender must comply with the transmix requirements of subpart F 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 L of this part.

(c) *Sampling, testing, and retention requirements.* A transmix blender must conduct sampling, testing, and sample retention in accordance with subparts F and N of this part.

§ 1090.155 Fuel additive manufacturers.

This section provides an overview of general requirements applicable to a fuel additive manufacturer. A gasoline additive manufacturer must comply with the requirements of paragraph (a) of this section. A diesel fuel additive manufacturer must comply with the requirements of paragraph (b) of this section. A certified ethanol denaturant producer must comply with the requirements of paragraph (c) of this section.

(a) *Gasoline additive manufacturers.* A gasoline additive manufacturer must meet the following requirements:

(1) *Gasoline additive standards.* A gasoline additive manufacturer must produce gasoline additives that comply with subpart C of this part.

(2) *Certification.* A gasoline additive manufacturer must certify the gasoline additives they produce under subpart K of this part.

(3) *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 L of this part.

(4) *Gasoline detergent manufacturers.* A gasoline detergent manufacturer must comply with the following requirements:

(i) *Part 79 registration and LAC determination.* A gasoline detergent manufacturer 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: 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 detergent standards.* Report the LAC determined under § 1090.260(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 L of this part.

(iv) *Sampling, testing, and retention requirements.* A gasoline detergent manufacturer that registers detergents must conduct sampling, testing, and sample retention in accordance with subpart N of this part.

(b) *Diesel fuel additive manufacturers.* A diesel fuel additive manufacturer must meet the following requirements:

(1) *Diesel fuel additive standards.* A diesel fuel additive manufacturer must produce diesel fuel additives that comply with subpart D of this part.

(2) *Certification.* A diesel fuel additive manufacturer must certify the diesel fuel additives they produce under subpart K of this part.

(3) *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 L of this part.

(c) *Certified ethanol denaturant producers and importers.* A certified ethanol denaturant producer or importer must meet the following requirements:

(1) *Certification.* A certified ethanol denaturant producer or importer must certify that certified ethanol denaturant meets the requirements in § 1090.275 using the procedures specified at § 1090.1000(g).

(2) *Registration.* A certified ethanol denaturant producer or importer 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 L of this part.

§ 1090.160 Distributors, carriers, and resellers.

A distributor, carrier, or reseller must comply with the requirements of this section.

(a) *Gasoline and diesel standards.* A distributor, carrier, or reseller must comply with the applicable requirements of subparts C and D of this part.

(b) *Registration.* A distributor or carrier 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 § 1090.515(g).

(c) *PTDs.* On each occasion when a distributor, carrier, or reseller transfers custody or title to any fuel, fuel additive, or regulated blendstock, the transferor must provide to the transferee PTDs under subpart L of this part.

§ 1090.165 Retailers and WPCs.

A retailer or WPC must comply with the requirements of this section.

(a) *Gasoline and diesel standards.* A retailer or WPC must comply with the applicable requirements of subparts C and D of this part.

(b) *Labeling.* A retailer or WPC that dispenses fuels requiring a label under this part must display fuel labels under subpart P of this part.

(c) *Fuels made through fuel dispensers.* A retailer or WPC that produces gasoline (*e.g.,* E15) through a fuel dispenser with anything other than PCG and DFE is also a blending manufacturer and must comply with the applicable requirements in § 1090.105.

§ 1090.170 Independent surveyors.

An independent surveyor that conducts fuel surveys must comply with the requirements of this section.

(a) *Survey provisions.* An independent surveyor must conduct fuel surveys under subpart O of this part.

(b) *Registration.* An independent surveyor must register with EPA under subpart I of this part.

(c) *Reporting.* An independent surveyor must submit reports to EPA under subpart J of this part.

(d) *Sampling, testing, and retention requirements.* An independent surveyor must conduct sampling, testing, and sample retention in accordance with subpart N of this part.

(e) *Independence requirements.* In order to perform a survey program under subpart O of this part, an independent surveyor must meet the independence requirements in § 1090.55.

§ 1090.175 Auditors.

An auditor that conducts an audit for a responsible party under this part must comply with the requirements of this section.

(a) *Registration.* An auditor must register with EPA under subpart I of this part.

(b) *Reporting.* An auditor must submit reports to EPA under subpart J of this part.

(c) *Attest engagement.* An auditor must conduct audits under subpart S of this part.

(d) *Independence requirements.* In order to perform an annual attest engagement under subpart S of this part, an auditor 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.

A pipeline operator must comply with the requirements of this section.

(a) *Gasoline and diesel standards.* A pipeline operator must comply with the applicable requirements of subparts C and D of this part.

(b) *PTDs.* On each occasion when a pipeline operator transfers custody or title to any fuel, fuel additive, or regulated blendstock, the transferor must provide to the transferee PTDs under subpart L of this part.

(c) *Transmix requirements.* A pipeline operator 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. A gasoline manufacturer, gasoline additive manufacturer (*e.g.,* an oxygenate or certified ethanol denaturant producer), or gasoline regulated blendstock producer (*e.g.,* a certified butane or certified pentane producer) must demonstrate compliance with the per-gallon standards in this subpart by measuring fuel parameters in accordance with subpart N of this part.

(c)(1) Except as specified in paragraph (c)(2) of this section, 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. A fuel manufacturer must demonstrate compliance with average standards by measuring fuel parameters in accordance with subpart N of this part and by determining compliance under subpart H of this part.

(2) The sulfur average standard in § 1090.205(a) and the benzene average standards in § 1090.210(a) and (b) do not apply to gasoline produced by the following:

(i) Truck and rail importers using the provisions of § 1090.1610 to meet the alternative per-gallon standards of §§ 1090.205(d) and 1090.210(c).

(ii) Certified butane blenders.

(iii) Certified pentane blenders.

(iv) Transmix blenders.

(v) Transmix processors that produce gasoline from only TGP or both TGP and PCG.

(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.

(f) No fuel or fuel additive manufacturer may introduce into commerce gasoline or gasoline additives (including oxygenates) that are not ''substantially similar'' under 42 U.S.C. 7545(f)(1) or permitted under a waiver granted under 42 U.S.C. 7545(f)(4).

§ 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.* A gasoline manufacturer 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. A gasoline manufacturer must 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.* (1) An importer that imports 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.

(2) An importer that imports gasoline by rail or truck but does not comply with the alternative sampling and testing requirements in § 1090.1610 must conduct sampling, testing, and sample retention in accordance with subpart N of this part and comply with the sulfur standards in paragraphs (a) and (b) 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.* A gasoline manufacturer must meet a benzene average standard of 0.62 volume percent for each compliance period.

(b) *Maximum benzene average standard.* A gasoline manufacturer 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.* (1) An importer that imports 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.

(2) An importer that imports gasoline by rail or truck that does not comply with the alternative sampling and testing requirements in § 1090.1610 must conduct sampling, testing, and sample retention in accordance with subpart N of this part and comply with the benzene 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)(1) *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 lower maximum RVP per-gallon standards specified in paragraphs (a)(2) through (5) of this section.

(2) *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)(2)—FEDERAL 7.8 PSI RVP AREAS

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.

(3) *RFG maximum RVP per-gallon standard.* Gasoline designated as Summer RFG or located in an RFG covered area during the summer season must meet a maximum RVP per-gallon standard of 7.4 psi.

(4) *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.

(5) *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)(1) or (2) 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 paragraph (a)(1) or (2) of 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 SIP-controlled gasoline 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 the person(s) who produced, imported, sold, offered for sale, distributed, offered to distribute, supplied, offered for supply, dispensed, stored, transported, or introduced the gasoline into commerce 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 WPC 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 RFG standards.

The standards in this section apply to gasoline that is designated as RFG or RBOB or that is used in an RFG covered area. 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) and the sulfur per-gallon standards in § 1090.205(b) and (c).

(b) *Benzene standards.* RFG or RBOB must comply with the benzene average standards in § 1090.210(a) and (b).

(c) *RVP standard.* Summer RFG or Summer RBOB must comply with the RFG RVP standard in § 1090.215(a)(3).

(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 must not be blended with Summer RFG or Summer RBOB under § 1090.1320.

§ 1090.225 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).

§ 1090.230 Limitation on use of gasoline-ethanol blends.

(a) No person may sell, introduce, cause or permit the sale or introduction of gasoline containing greater than 10 volume percent ethanol (*e.g.,* E15) 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 engine, vehicle, 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.

§ 1090.250 Certified butane standards.

Butane designated as certified butane under § 1090.1000(e) for use under the butane blending provisions of § 1090.1320(b) must meet the following per-gallon standards:

(a) *Butane content.* Minimum 85 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.

§ 1090.255 Certified pentane standards.

Pentane designated as certified pentane under § 1090.1000(f) for use under the pentane blending provisions of § 1090.1320(b) 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.

§ 1090.260 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 that meets the requirements of paragraph (b) of this section at a rate at least as high as the detergent's LAC over the 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). A party compliant with this paragraph (b)(2) is exempt from the port fuel injector deposit control requirements of 40 CFR 80.165(a).

(3) A gasoline detergent manufacturer 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.

§ 1090.265 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 that 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 sulfur per-gallon standard in § 1090.205(c), if all the following conditions are met:

(1) The fuel additive blender blends gasoline additives into gasoline at a concentration less than or equal to a combined total of 1.0 volume percent.

(2) The fuel additive blender does not add any other blendstock into the gasoline except for oxygenates that meet the requirements in § 1090.270.

(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 a gasoline manufacturer under this part.

(d) Any gasoline additive used or intended for use to comply with the gasoline deposit control requirement in § 1090.260(a) must meet the gasoline deposit control standards under § 1090.260(b).

§ 1090.270 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 § 1090.275 may be used as denaturants.

(2) *Denaturant concentration.* The concentration of all denaturants used in DFE must not exceed 3.0 volume percent.

§ 1090.275 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.* In addition to the requirements of paragraph (a) of this section, certified ethanol denaturant must meet the following requirements:

(1) *Sulfur content per-gallon standard.* Maximum 330 ppm. If the certified ethanol denaturant producer represents a batch of denaturant as having a maximum sulfur content less than 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.

§ 1090.285 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)—RFG COVERED AREAS UNDER 42 U.S.C. 7545(k)(10)(D)

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)—ADDITIONAL RFG COVERED AREAS UNDER 42 U.S.C. 7545(k)(10)(D)

Area designation	State or district	Counties	Independent cities
Washington, DC-Maryland-Virginia.	District of Columbia	Washington.	
	Maryland	Calvert, Charles, Frederick, Montgomery, Prince George's.	
	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].	

TABLE 2 TO PARAGRAPH (b)—ADDITIONAL RFG COVERED AREAS UNDER 42 U.S.C. 7545(k)(10)(D)—Continued

Area designation	State or district	Counties	Independent cities
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)—RFG COVERED AREAS UNDER 42 U.S.C. 7545(k)(6)(A)(i)

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)—RFG COVERED AREAS UNDER 42 U.S.C. 7545(k)(6)(A)(i)—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)—RFG COVERED AREAS UNDER 42 U.S.C. 7545(k)(6)(B)(i)(I)

State	Counties
Maine	Androscoggin, Cumberland, Kennebec, Knox, Lincoln, Sagadahoc, York.

§ 1090.290 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 will become 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 do all the following:

(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 required 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 required by 42 U.S.C. 7545(k)(6)(B)(i). EPA must do all the following:

(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 required 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 a 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 either the removal of an RFG opt-in area (or portion of an RFG opt-in area), or the removal of a covered area (or portion of a covered area) under 42 U.S.C. 7545(k)(10)(D) that meets the

criteria in paragraph (c) of this section, from the list of RFG covered areas in § 1090.285 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 the governor's authorized representative, and must include all the following:

(i) A geographic description of each RFG area (or portion of each RFG area) that is covered by the request.

(ii) A description of all the means 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 an RFG area 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 the governor's 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, or the governor's authorized representative, 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, or the governor's authorized representative, 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 an RFG opt-out request and its effective date.

(5) Upon the effective date for the removal of an RFG area (or portion of an RFG 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 § 1090.285.

§ 1090.295 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 RVP 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 the governor's 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) that is covered by the request.

(2) A description of all the means 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 the governor's 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 RVP standard as requested by the governor, or the governor's authorized representative, 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 RVP standard as requested by the governor, or the governor's authorized representative, 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 RVP 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 RVP standard in § 1090.215(a)(2).

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) A diesel fuel manufacturer or diesel fuel additive manufacturer must demonstrate compliance with the standards in this subpart by measuring fuel parameters in accordance with subpart N 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 does not meet any standard set forth in this subpart.

(2) Notwithstanding paragraph (e)(1) of this section, an importer 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 each new batch of diesel fuel under § 1090.1000(c) and demonstrates that it complies with the standards in this subpart by measuring fuel parameters in accordance with subpart N of this part before custody or title to each new batch of diesel fuel is transferred.

(f) No fuel or fuel additive manufacturer may introduce into commerce diesel fuel or diesel fuel additives that are not ''substantially similar'' under 42 U.S.C. 7545(f)(1) or permitted under a waiver granted under 42 U.S.C. 7545(f)(4).

(g) Distillate global marine fuel that does not qualify for an exemption under § 1090.650 is subject to the standards, requirements, and prohibitions that apply for ULSD under this part.

(h) 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), 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 of 35 volume percent.

§ 1090.310 Diesel fuel additives standards.

(a) Except as specified in paragraph (b) and (c) of this section, diesel fuel additives blended into diesel fuel that is subject to the standards in § 1090.305 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 diesel fuel in a quantity less than 1.0 volume percent of the resultant mixture of additive and diesel fuel.

(2) The PTD for the diesel fuel additive complies with the requirements in § 1090.1120(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, ECA marine fuel, and jet fuel provisions.

Heating oil, kerosene, ECA marine fuel, and jet fuel must not be sold for use in motor vehicles or nonroad equipment and are not subject to the ULSD standards in § 1090.305 unless also designated as ULSD under § 1090.1015(a).

§ 1090.320 500 ppm LM diesel fuel standards.

(a) *Overview.* 500 ppm LM diesel fuel produced or distributed by a transmix processor or pipeline operator under § 1090.515 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).

§ 1090.325 ECA marine fuel standards.

(a) *Overview.* Except as specified in paragraph (c) of this section, ECA marine fuel must meet the per-gallon standards of this section.

(b) *Sulfur standard.* Maximum sulfur content of 1,000 ppm.

(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 exempts or excludes the vessel 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 Gasoline produced from blending transmix into PCG.

(a) *Applicability.* (1) Except as specified in paragraph (a)(2) of this section, a transmix blender that blends transmix into PCG must comply with the requirements of this section.

(2) 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 requirements in this section.

(b) *Requirements.* (1) The distillation end-point of the resultant transmix-blended gasoline must not exceed 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 that meets the requirements of paragraph (c) of this section.

(5) In the event that the test result for any sample collected under the quality assurance program specified in

paragraph (c) of this section indicates that the gasoline does not comply with any of the applicable standards in this part, the transmix blender must do all the following:

(i) Immediately take steps to stop the sale of the gasoline that was sampled.

(ii) Take reasonable steps to determine the cause of the noncompliance and prevent future instances of noncompliance.

(iii) Notify EPA of the noncompliance.

(iv) 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.

(c) *Quality assurance program.* (1) The quality assurance program must be designed to assure that the type and amount of transmix blended into PCG will not cause violations of the applicable fuel quality standards.

(2) Except as specified in paragraph (c)(3) of this section, as a part of the quality assurance program, a transmix blender must collect samples of gasoline after blending transmix and test the samples to ensure the end-point temperature of the resultant transmix-blended gasoline does not exceed 437 degrees Fahrenheit, using one of the following sampling methods:

(i) For transmix that is blended in a tank (including a tank on a barge), collect a representative sample of the resultant transmix-blended gasoline following each occasion transmix is blended.

(ii) For transmix that is blended by a computer controlled in-line blending system, the transmix blender must collect composite samples of the resultant transmix-blended gasoline at least twice each calendar month during which transmix is blended.

(3) Any transmix blender may petition EPA for approval of a quality assurance program that does not include the minimum sampling and testing requirements of paragraph (c)(2) 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:

(i) 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.

(ii) 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.

(iii) A transmix blender that petitions 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.

§ 1090.505 Gasoline produced from TGP.

(a) *General provisions.* (1) A transmix processor or blending manufacturer that produces gasoline from TGP must meet the requirements of this section.

(2) A transmix processor must not use any feedstock other than transmix to produce TGP.

(3) A transmix processor or blending manufacturer 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. A transmix processor or blending manufacturer may also blend fuel additives into gasoline in accordance with §§ 1090.260 and 1090.265.

(b) *Demonstration of compliance with sulfur per-gallon standard.* (1) A transmix processor or blending manufacturer that produces gasoline with TGP must meet one of the following sulfur standards for each batch of gasoline they produce, as applicable:

(i) Each batch of gasoline produced from only TGP or both TGP and PCG must comply with the downstream sulfur per-gallon standard in § 1090.205(c).

(ii) 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).

(2) A transmix processor or blending manufacturer that produces gasoline with TGP must demonstrate compliance with the applicable sulfur standard in paragraph (b)(1) of this section by measuring the sulfur content of each batch of gasoline they produce in accordance with subpart N of this part.

(c) *Demonstration of compliance with sulfur and benzene average standards.* (1) A transmix processor or blending manufacturer that produces gasoline with TGP must exclude TGP and PCG used to produce gasoline under the provisions of this section from their compliance calculations to demonstrate compliance with the sulfur and benzene average standards in §§ 1090.205(a) and 1090.210(a) and (b), respectively. A transmix processor or blending manufacturer that exclusively produces gasoline from only TGP or both TGP and PCG is deemed to be in compliance with the sulfur and benzene average standards in §§ 1090.205(a) and 1090.210(a) and (b), respectively.

(2) A transmix processor or blending manufacturer that produces gasoline with TGP must include all blendstocks other than TGP and PCG in their compliance calculations to demonstrate compliance with the sulfur and benzene average standards in §§ 1090.205(a) and 1090.210(a) and (b), respectively.

(3) A transmix processor or blending manufacturer that produces gasoline by adding blendstock to TGP must comply with § 1090.1325.

(d) *Demonstration of compliance with RVP standard.* A transmix processor or blending manufacturer that produces gasoline with TGP 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 N of this part.

(e) *Distillation point determination.* A transmix processor or blending manufacturer that produces gasoline with TGP must determine the following distillation parameters for each batch of gasoline they produce in accordance with subpart N of this part:

(1) T10.

(2) T50.

(3) T90.

(4) End-point.

(5) Distillation residue.

§ 1090.510 Diesel and distillate fuel produced from TDP.

(a) A transmix processor must not use any feedstock other than transmix to produce TDP.

(b) A transmix processor must demonstrate that each batch of diesel fuel or distillate fuel produced from TDP meets the applicable standard in subpart D of this part and must comply with all other requirements applicable to a diesel fuel or distillate fuel manufacturer under this part.

(c) A transmix processor that produces 500 ppm LM diesel fuel from

TDP must also comply with the requirements in § 1090.515.

§ 1090.515 500 ppm LM diesel fuel produced from TDP.

(a) *Applicability.* A transmix processor that produces 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.* A transmix processor 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.* A party that handles 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) 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 or marine engines that are not required to use ULSD under 40 CFR 1033.815 or 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.* A transmix processor or distributor must segregate 500 ppm LM diesel fuel from other fuels except as follows:

(1) A pipeline operator 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) A WPC or retailer 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 resultant 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 in order to comply with the segregation requirement in 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 will handle the 500 ppm LM diesel fuel through to the ultimate consumer.

(4) Identify all ultimate consumers that will be 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.

§ 1090.520 Handling practices for pipeline interface that is not transmix.

(a) Subject to the limitations in paragraph (b) of this section, a pipeline operator 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, a pipeline operator must 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, a pipeline operator must not cut pipeline interface from a batch of RFG shipped adjacent to a batch of conventional gasoline into the batch of RFG.

Subpart G—Exemptions, Hardships, and Special Provisions

§ 1090.600 General provisions.

(a) Gasoline, diesel fuel, or IMO marine fuel subject to an exemption under this subpart is exempt from the standards and provisions of this part as specified in this subpart.

(b) Fuel that does not meet 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 or 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 or 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 that meet the requirements of subpart L 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 dispenser stand, fueling truck, or tank that is labeled with the appropriate designation of the fuel.

(4) It must 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 that the exemption is for an appropriate R&D purpose.

(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.

(5) Meet the requirements specified in paragraphs (c) and (d) of this section.

(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 that meets the requirements of subparts C and D of this part, as applicable, and how fuel dispensers will be labeled to ensure that the fuel is not dispensed for use in motor vehicles or nonroad engines, vehicles, or equipment, including locomotive or marine engines, that are part of the R&D test program.

(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 (c), 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 the requirements of subpart L of this part.

(2) The fuel must be designated as exempt fuel by the fuel manufacturer or supplier, as applicable.

(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 retail outlet or 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 approval 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 an approval for 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 with the requirements of this section.

(3) 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.

(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 on any fuel dispenser from which the 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 or marine engines, except for those used only in aircraft or in sanctioned racing events.

§ 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 ECA 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 that meet the requirements of subpart L of this part.

(d) The fuel is completely segregated from non-exempt fuel at all points 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 segregated from fuel that is not California gasoline or diesel fuel at all points in the distribution system.

(3) Except for as specified in paragraph (d) or (e) of this section, 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 L 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 M of this part.

(6) California gasoline or diesel fuel must 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 must do one of the following:

(1) Comply with the sampling and testing provisions in subpart N of this part, as applicable.

(2) Sample and test using methods approved in Title 13 of the California Code of Regulations.

(3) Sample and test per a current and valid protocol agreement between the fuel manufacturer and the California Air Resources Board or by Executive Order from the California Air Resources Board. Such protocols or Executive Orders must be provided to EPA upon request.

(d) *California gasoline used outside of California.* California gasoline may be used in any part of the United States outside of the state of California if the manufacturer or distributor of the California gasoline does one of the following:

(1) Recertifies the California gasoline as gasoline under this part and includes the recertified gasoline in their average standard compliance calculations.

(2) Designates the California gasoline as gasoline under this part without recertification and does all the following:

(i) Demonstrates that the fuel meets all applicable requirements for California reformulated gasoline under Title 13 of the California Code of Regulations.

(ii) Properly redesignates the fuel under § 1090.1010(b)(2)(vi).

(iii) Generates PTDs under subpart L of this part.

(iv) Keeps records under subpart M of this part.

(v) Does not include the California gasoline in their average standard compliance calculations.

(e) *California diesel used outside of 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 the fuel does all the following:

(1) The manufacturer or distributor properly redesignates the fuel under § 1090.1015(b)(3)(iii).

(2) The manufacturer or distributor generates PTDs under subpart L of this part.

(3) The manufacturer or distributor keeps records under subpart M 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 that meet the requirements of subpart L of this part.

(d) The summer gasoline is completely segregated from non-exempt gasoline at all points 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 temporary shortfalls in the supply of the fuel in a state or region of the United States for which the shortfall is 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 shows how compliance will be achieved as expeditiously as possible.

(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 and accurate 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 § 1090.260.

(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.

(a) 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:

(1) The fuel, fuel additive, or regulated blendstock is designated for export by the fuel manufacturer, fuel additive manufacturer, or regulated blendstock producer.

(2) The fuel, fuel additive, or regulated blendstock designated for export is accompanied by PTDs that meet the requirements of subpart L of this part.

(3) The fuel manufacturer, fuel additive manufacturer, or regulated blendstock producer keeps records that demonstrate that the fuel, fuel additive, or regulated blendstock was ultimately exported from the United States.

(4) The fuel, fuel additive, or regulated blendstock is completely segregated from non-exempt fuels, fuel additives, and regulated blendstocks from the point the fuel, fuel additive, or regulated blendstock is designated for export to the point where it is ultimately exported from the United States.

(5) Fuel, fuel additive, or regulated blendstock certified and designated for export may be certified for use in the United States if all the applicable requirements of this part are met.

(b) 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) Exempt distillate global marine fuel under paragraph (a) of this section must meet all the following requirements:

(1) The fuel must not exceed 0.50 weight percent sulfur (5,000 ppm).

(2) The fuel must be accompanied by PTDs as specified in § 1090.1115.

(3) The fuel must be designated as specified in § 1090.1015.

(4) The fuel must be segregated from non-exempt fuel at all points in the distribution system.

(5) The fuel must not be used in vehicles, engines, or equipment other than those referred to in paragraph (a) of this section.

(c)(1) Fuel that does not meet 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 M of this part must 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, a gasoline manufacturer 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:

$$CSV_y = S_{tot,y} + Ds_{,(y-1)} + D_{S\_Oxy\_Total} - C_S$$

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)(2), 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, a gasoline manufacturer 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:

$$CBV_y = B_{tot,y} + D_{Bz,(y-1)} + D_{Bz\_Oxy\_Total} - C_{Bz}$$

Where:

CBV_y = Compliance benzene value for compliance period 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.

$D_{Bz\_Oxy\_Total}$ = The 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.

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 compliance period y if the following equation is true:

$B_{a,y} \leq 1.30$ vol%

(5) *Rounding and reporting benzene values.* (i) The total amount of benzene produced, as calculated in paragraph (b)(1)(ii) of this section, must be rounded to the nearest whole benzene gallon in accordance with § 1090.50.

(ii) The average benzene concentration, as 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 content and benzene content in compliance calculations under this subpart.

(d) *Inclusions.* A gasoline manufacturer 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 under § 1090.1320(a)(1), include the PCG batch as a batch with a negative volume, positive sulfur content, and positive benzene content and include the new batch of gasoline as a batch with a positive volume, positive sulfur content, and positive benzene content in compliance calculations under this section. Any negative compliance sulfur value or compliance benzene value must be reported as zero and not as a negative result.

(ii) For PCG by addition under § 1090.1320(a)(2), include only the blendstock added to make the new batch of gasoline as a batch with a positive volume, positive sulfur content, and positive benzene content 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)(i) 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. 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.

(ii) For PCG by subtraction under § 1090.1320(a)(1), include PCG in the compliance period in which it was blended with blendstock. This may necessitate reporting a portion of the volume of PCG received in one compliance period as a separate PCG batch in the following compliance period.

(e) *Exclusions.* A gasoline manufacturer must exclude the following products from their compliance calculations:

(1) Gasoline that was not produced by the gasoline manufacturer.

(2) Blendstock, unless the 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(b).

(5) TGP.

(6) GTAB that meets the requirements in § 1090.1615(a).

(7) Gasoline imported by truck or rail using the provisions of § 1090.1610 to meet the alternative per-gallon standards of §§ 1090.205(d) and 1090.210(c).

(8) Gasoline exempt 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, a gasoline manufacturer must comply with average standards at the individual facility level.

(b) A gasoline importer must comply with average standards at the company level, except that aggregation of all import facilities within a PADD as a single facility is required for compliance with the maximum benzene average standard in § 1090.210(b).

§ 1090.710 Downstream oxygenate accounting.

The requirements of this section apply to BOB for which a gasoline manufacturer accounts for the effects of the oxygenate blending that occurs downstream of the fuel manufacturing facility in the gasoline manufacturer's average standard compliance calculations under this subpart. This section also includes requirements for oxygenate blenders 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) For each batch of BOB produced or imported, create a hand blend in accordance with § 1090.1340 and determine the properties of the hand blend using the methods specified in subpart N of this part.

(3) Participate in the NSTOP specified in § 1090.1450 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 on the PTD for the BOB each oxygenate type and amount (or range of amounts) for which the hand blend was certified for compliance under § 1090.1340.

(6) Participate in the NFSP under subpart O of this part.

(b) *Requirements for oxygenate blenders.* An oxygenate blender 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 must not include the volume, sulfur content, 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 recertify BOB for use as gasoline without the addition of the specified type and amount of oxygenate if the provisions of § 1090.740 are met. A person who recertifies BOB for use as gasoline without the addition of the specified type and amount of oxygenate is a gasoline manufacturer and must meet all applicable requirements for a gasoline manufacturer 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 (a)(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)(i), 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) A gasoline manufacturer 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) A gasoline manufacturer that incurs a deficit under this section must satisfy that deficit and demonstrate compliance with the annual average standards 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 a gasoline manufacturer 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. A gasoline manufacturer may also bank credits for future use, transfer credits to another facility within the 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 must 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 incurring a compliance deficit under § 1090.715.

(3) Credits must not be used to meet per-gallon standards.

(4) Credits must not be used to meet the maximum benzene average standard in § 1090.210(b).

(5) Credits may only be used if the gasoline manufacturer owns them at the time of use.

(d) *Credit reporting.* A gasoline manufacturer that generates, transacts, or uses credits under this subpart must report to EPA as specified in § 1090.905 using forms and procedures specified by EPA.

(e) *Part 80 credit use.* Valid credits generated under 40 CFR 80.1615 and 80.1290 may be used by a gasoline manufacturer 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) No person other than a gasoline manufacturer may generate credits for use towards an average standard specified in subpart C of this part.

(2) No credits may be generated for gasoline produced by any of the following activities:

(i) Transmix processing.
(ii) Transmix blending.
(iii) Oxygenate blending.
(iv) Certified butane blending.
(v) Certified pentane blending.
(vi) 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)(i), 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.* A gasoline manufacturer may only generate credits after they have finished producing or importing gasoline for the compliance period.

(f) *Credit generation reporting.* A gasoline manufacturer that generates credits under this section must report to EPA all credit generation information as specified in § 1090.905 using forms and procedures specified by EPA.

§ 1090.730 Credit transfers.

A gasoline manufacturer may only transfer or 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 in accordance with the limitations on credit use specified in § 1090.720(c).

(c) Any credit transfer must take place no later than the deadline specified in § 1090.900(c) following the compliance period in which 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'') must 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 year(s) 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 must 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 must not be used to achieve compliance with an average standard under this part, 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) A gasoline manufacturer 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) A gasoline manufacturer must comply with applicable requirements of this part and incur deficits to be included in their compliance calculations in § 1090.700 for each facility at which the gasoline manufacturer recertifies BOB.

(3) Unless otherwise required under this part, a gasoline manufacturer that recertifies 1,000,000 or less gallons of BOB under this section at a facility does not need to obtain credits to satisfy deficits incurred under this section or arrange for an auditor to conduct audits under subpart S of this part for that facility. The gasoline manufacturer must still comply with all other applicable provisions of this part (*e.g.,* register and submit reports under subparts I and J of this part, respectively).

(4) A party that only recertifies BOB that contains a greater amount of a specified oxygenate (*e.g.,* a party adds 15 volume percent DFE instead of 10 volume percent to an E10 BOB) or a different oxygenate at an equal or greater amount (*e.g.,* a party adds 16 volume percent isobutanol instead of 10 volume percent to an E10 BOB) does not incur deficits under this section, does not need to submit reports under subpart J of this part, and does not need to arrange for an auditor to conduct an audit under subpart S of this part. The party must still comply with all other applicable provisions of this part (*e.g.,* register and keep records under subparts I and M of this part, respectively).

(b) A gasoline manufacturer that recertifies 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:

$$D_{S\_Oxy\_Batch} = 11\text{ppm} \cdot V_{Base} \cdot \left[\frac{1}{\left(1 - (PTD_{Oxy} - ACTUAL_{Oxy})\right)} - 1\right]$$

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.

$ACTUAL_{Oxy}$ = The volume fraction of oxygenate that was actually added to the BOB. If no oxygenate was added to the BOB, then $ACTUAL_{Oxy} = 0$.

(2) *Total sulfur deficit from downstream BOB recertification.* Calculate the total sulfur deficit from downstream BOB recertification for each facility 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:

$$D_{Bz\_Oxy\_Batch} = 0.0068 \cdot V_{Base} \cdot \left[\frac{1}{\left(1 - (PTD_{Oxy} - ACTUAL_{Oxy})\right)} - 1\right]$$

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.

$ACTUAL_{Oxy}$ = The volume fraction of oxygenate that was actually added to the BOB. If no oxygenate was added to the BOB, then $ACTUAL_{Oxy} = 0$.

(4) *Total benzene deficit from downstream BOB recertification.* Calculate the total benzene deficit from downstream BOB recertification for each facility 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) A gasoline manufacturer does 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 must not be carried forward under § 1090.715.

§ 1090.745 Informational annual average calculations.

(a) A gasoline manufacturer must calculate and report annual average sulfur and benzene concentrations for each of their facilities as specified in this section. The values calculated and reported under this section are not used to demonstrate compliance with average standards under this part.

(b) A gasoline manufacturer must calculate and report their unadjusted average sulfur concentration 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 concentration for compliance period y, in ppm. Round and 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) A gasoline manufacturer must calculate and report their net average sulfur concentration as follows:

$$S_{NET,y} = \frac{CSV_y}{\sum_{i=1}^{n} V_i}$$

Where:

$S_{NET,y}$ = The facility net average sulfur concentration for compliance period y, in ppm. Round and report $S_{NET,y}$ to two decimal places.

CSV_y = Compliance sulfur value for compliance period y, per § 1090.700(a)(1), in ppm-gallons.

(d) A gasoline manufacturer must calculate and report their net average benzene concentration as follows:

$$B_{NET,y} = \frac{CBV_y}{\sum_{i=1}^{n} V_i}$$

Where:

$B_{NET,y}$ = The facility net average benzene concentration for compliance period y, in volume percent benzene. Round and report $B_{NET,y}$ to two decimal places.

CBV_y = Compliance benzene value for compliance period y, per § 1090.700(b)(1)(i), in benzene gallons.

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 that are part of the 500 ppm LM fuel distribution chain under a compliance plan submitted under § 1090.515(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, a party not currently registered with EPA must register with EPA no later than 60 days in advance of the first date that such party engages in any activity under this part requiring registration under paragraph (a) of this section.

(2) *Existing registrants.* Any party that is already registered with EPA under 40 CFR part 80 as of January 1, 2021, is deemed to be registered for purposes of this part, except that such party is 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) *RCO submission.* Registration information must be submitted by 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.

(e) *Forms and procedures for registration.* All registrants must use forms and procedures specified by EPA.

(f) *Company and facility identification.* EPA will provide registrants with company and facility identifiers to be used for recordkeeping and reporting under this part.

(g) *English language.* Registration information submitted to EPA must be in English.

§ 1090.805 Contents of registration.

(a) *General information required for all registrants.* A party required to register under this part must submit all the following general information to EPA:

(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.

(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, email address, 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 an importer, 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, a certified pentane producer 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 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 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 M 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, or any of a party's facilities, 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 (42 U.S.C. 7414 or 7542) 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 under subpart M 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, EPA may deactivate the registration of the party without any notice to the party. EPA will provide written notification to the RCO identifying the reason(s) 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 M 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 the 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 company or 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 company or 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.

(3) Reported volumes must be temperature-corrected in accordance with § 1090.1350(d).

(4) Report values as specified in § 1090.1335(e).

(b) *English language.* All reports submitted under this subpart must be submitted in English.

(c) *Report deadlines.* All annual, batch, and credit transaction 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 paragraph (a)(4) in § 1090.925.

(d) *RCO submission.* Reports must be signed and submitted by an RCO or their delegate of the RCO.

§ 1090.905 Annual, batch, and credit transaction reporting for gasoline manufacturers.

(a) *Annual compliance demonstration for sulfur.* For each compliance period, a gasoline manufacturer must submit a report for each of their facilities 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 in order to administer reporting systems.

(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 concentration, per § 1090.745(c), in ppm.

(vii) Any other information as EPA may require in order to administer reporting systems.

(b) *Annual compliance demonstration for benzene.* For each compliance period, a gasoline manufacturer must submit a report for each of their facilities 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 in order to administer reporting systems.

(2) *Facility-level reporting.* For each fuel manufacturing facility or importer, as applicable:

(i) The EPA-issued company and facility identifiers.

(ii) The compliance benzene value, per § 1090.700(b)(1)(i), 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. For an importer, report the average benzene concentration for each aggregated import facility.

(v) The net average benzene concentration, 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 in order to administer reporting systems.

(c) *Batch reporting.* A gasoline manufacturer must report the following information for each of their facilities on a per-batch basis for gasoline and gasoline regulated blendstocks:

(1) For all gasoline for which the gasoline manufacturer has not accounted for oxygenate added downstream under § 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 as RFG, CG, RFG ''Intended for Oxygenate Blending'', or CG ''Intended for Oxygenate Blending''.

(vi) The tested sulfur content of the batch separately for per-gallon and average compliance, 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.

(viii) For all batches of summer gasoline:

(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. If the gasoline is Summer RFG that is designated as ''Intended for Oxygenate Blending'' under § 1090.1010(a)(4), report the tested RVP for the hand blend.

(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 for which the gasoline manufacturer has accounted for oxygenate added downstream under § 1090.710:

(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 a gasoline manufacturer 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. If the PCG is a BOB, report the tested sulfur content of the hand blend prepared under § 1090.1340.

(G) The tested benzene content of the batch, as a volume percentage, and the test method used to measure the benzene content. If the PCG is a BOB, report the tested benzene content of the hand blend prepared under § 1090.1340.

(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(s) added to PCG by a gasoline manufacturer complying by addition under § 1090.1320(a)(2), report each blendstock as a separate batch and all the following:

(i) For the blendstock, the sulfur content and benzene content of the batch.

(ii) For batches produced by adding blendstock to PCG, the sulfur content, oxygenate type and amount (unless not required under § 1090.1310(e)), and for summer gasoline, RVP, of the batch.

(5) For certified butane blended by a certified butane blender or certified pentane blended by a certified pentane blender:

(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 volume of certified butane or certified pentane blended, 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 certified butane or certified pentane supplier.

(F) The sulfur content of the batch, in ppm, provided by the certified butane or certified pentane supplier.

(G) The benzene content of the batch, in volume percent, provided by the certified butane or certified pentane supplier.

(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) For a new batch of gasoline (*e.g.,* a blended gasoline containing certified butane and PCG) that is summer gasoline or summer BOB, the tested RVP of the batch, in psi, and the test method used to measure the RVP.

(6) For gasoline produced by adding any blendstocks to TGP:

(i) For each batch of gasoline produced with TGP, the sulfur content and for summer gasoline, RVP, of the batch.

(ii) For blendstocks added to TGP, a transmix processor or blending manufacturer must treat the TGP like PCG and report 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) For each batch of gasoline produced by a transmix processor or blending manufacturer from only TGP or both TGP and PCG under § 1090.505:

(i) The EPA-issued company and facility identifiers.

(ii) The batch number.

(iii) The date the batch was produced.

(iv) The batch volume, in gallons.

(v) The designation of the gasoline.

(vi) The tested sulfur content of the batch, in ppm, and the test method used to measure the sulfur content.

(vii) For summer gasoline:

(A) The applicable RVP standard in § 1090.215.

(B) The tested RVP of the batch, in psi, and the test method used to measure the RVP.

(9) Any other information as EPA may require in order to administer reporting systems.

(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 in order to administer reporting systems.

§ 1090.910 Reporting for gasoline manufacturers that recertify BOB to gasoline.

A party that recertifies BOB under § 1090.740 must report the information of this section, as applicable.

(a) *Batch reporting.* (1) A party that recertifies a BOB under § 1090.740 with less oxygenate than specified by the BOB manufacturer must report the following for each batch:

(i) The EPA-issued company and facility identifiers for the recertifying party.

(ii) The batch number assigned by the recertifying party.

(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 0.68 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) A party that recertifies a BOB under § 1090.740 with more oxygenate than specified by the BOB manufacturer does not need to report the batch.

(b) *Annual sulfur and benzene compliance reporting.* A party 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.* A party 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.

An oxygenate producer, for each of their production facilities, or an 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 § 1090.275.

(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 in order to administer reporting systems.

§ 1090.920 Reports by certified pentane producers.

A certified pentane producer 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 in order to administer reporting systems.

§ 1090.925 Reports by independent surveyors.

(a) *General procedures.* An independent surveyor must meet the following requirements:

(1) Electronically submit any plans, notifications, or reports required under this part using forms and procedures specified by EPA.

(2) For each report required under this section, affirm that the survey was conducted in accordance with an EPA-approved survey plan and that the survey results are accurate.

(3) Include EPA-issued company identifiers on each report required under this section.

(4) Submit quarterly reports required under paragraphs (b) and (d) of this section by the following deadlines:

TABLE 1 TO PARAGRAPH (a)(4)—QUARTERLY REPORTING DEADLINES

Calendar quarter	Time period covered	Quarterly report deadline
Quarter 1	January 1–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) *NFSP quarterly reporting.* An independent surveyor conducting the NFSP under § 1090.1405 must submit the following information quarterly, as applicable:

(1) For each retail outlet sampled by the independent surveyor:

(i) The identification information for the retail outlet, as assigned by the surveyor in a consistent manner and as specified 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.

(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, 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 in order to administer reporting systems.

(c) *NFSP annual reporting.* An independent surveyor conducting the NFSP under § 1090.1405 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 in order to administer reporting systems.

(d) *NSTOP quarterly reporting.* An independent surveyor conducting the NSTOP under § 1090.1450 must submit the following information quarterly, as applicable:

(1) For each gasoline manufacturing facility sampled by the independent surveyor:

(i) The EPA-issued company and facility identifiers for the gasoline manufacturer and the gasoline manufacturing facility.

(2) For each gasoline sample collected by the independent surveyor:

(i) The designation of the gasoline.

(ii) The date and time the independent surveyor collected the sample.

(iii) The batch number or the sample identification number as assigned by the independent surveyor in a consistent manner and as specified in the survey plan.

(iv) A description of any instance in which the gasoline manufacturer did not follow the applicable sampling procedures.

(v) The test results for the sample, and the test methods used, as determined by the independent surveyor, including the following parameters:

(A) The sulfur content, in ppm.

(B) The benzene content, in volume percent.

(C) The RVP in psi, if tested.

(vi) The test results for the sample, and the test methods used, as determined by the gasoline manufacturer, including the following parameters:

(A) The sulfur content, in ppm.

(B) The benzene content, in volume percent.

(C) The RVP in psi, if tested.

(vii) If available, the test results for the sample, and the test methods used, as determined by EPA's National Vehicle and Fuel Emissions Laboratory, including the following parameters:

(A) The sulfur content, in ppm.

(B) The benzene content, in volume percent.

(C) The RVP in psi, if tested.

(viii) The determined site precision under § 1090.1450(c)(10)(i) and the test performance index under § 1090.1450(c)(10)(ii) for each method and instrument that the gasoline manufacturer used to test the sample.

(ix) The reproducibility of each method that the gasoline manufacturer used to test the sample.

(x) Any applicable correlation equations used to compare the gasoline manufacturer's test results to the independent surveyor's test results.

(3) Any other information as EPA may require in order to administer reporting systems.

§ 1090.930 Reports by auditors.

(a) Attest engagement reports required under subpart S of this part must be submitted by an independent auditor registered with EPA and associated with a company, or companies, through 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 S of this part and the attest engagement report must clearly identify the methodologies followed and any findings, exceptions, and variances.

(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) The auditor must submit written acknowledgement from the RCO that the gasoline manufacturer has reviewed the attest engagement report.

§ 1090.935 Reports by diesel fuel manufacturers.

(a) *Batch reporting.* (1) For each compliance period, a ULSD manufacturer must submit the following information:

(i) The EPA-issued company and facility identifiers for the ULSD manufacturer.

(ii) The highest sulfur content observed for a batch of ULSD produced during the compliance period on a company level, in ppm.

(iii) The average sulfur concentration 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 and Designation

§ 1090.1000 Batch certification requirements.

(a) *General provisions.* (1) A fuel manufacturer, fuel additive

manufacturer, or regulated blendstock producer must certify batches of fuel, fuel additive, or regulated blendstock as specified in this section.

(2) A fuel manufacturer, fuel additive manufacturer, or regulated blendstock producer does not need to certify fuel, fuel additive, or regulated blendstock that is exempt under subpart G of this part.

(3)(i) For purposes of this part, the volume of a batch is one of the following:

(A) 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.

(B) The entire volume of a tank or vessel may be certified as a single batch. In such cases, any heel left in the tank or vessel after shipments of the batch becomes PCG.

(ii) If a volume of fuel, fuel additive, or regulated blendstock is placed in a tank, certified (if not previously certified), and is not altered in any manner, then it is considered to be the same batch even if several shipments or transfers are made out of that tank.

(iii) Batch volumes must be temperature-corrected in accordance with § 1090.1350(d).

(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 in § 1090.1337 and is produced during a period not to exceed 10 days.

(5) A fuel manufacturer must certify each batch of fuel at the facility where the fuel is produced or at a facility that is under the complete control of the fuel manufacturer before they transfer custody or title of the fuel to any other person.

(6) No person may sell, offer for sale, distribute, offer to distribute, supply, offer for supply, dispense, store, transport, or introduce into commerce gasoline, diesel fuel, or ECA marine fuel that is not certified under this section.

(b) *Gasoline.* (1) A gasoline manufacturer must certify gasoline as specified in paragraph (b)(2) of this section prior to introduction into commerce.

(2) To certify batches of gasoline, a gasoline manufacturer must comply with 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 N of this part. A transmix processor 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 § 1090.1020.

(iv) Designate batches of gasoline as specified in § 1090.1010.

(3) PCG may be mixed with other PCG without re-certification if the resultant mixture complies with the applicable standards in subpart C of this part and is accurately and clearly designated under § 1090.1010. Resultant 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 comply with one of the following:

(i) Designate the resultant mixture as meeting the least stringent RVP designation of any batch that is mixed. For example, a distributor that 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 N of this part and designate the new batch under § 1090.1010 to reflect the RVP of the resultant 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) A diesel fuel or ECA marine fuel manufacturer must certify diesel fuel or ECA marine fuel as specified in paragraph (c)(2) of this section prior to introducing the fuel into commerce.

(2) To certify batches of diesel fuel or ECA marine fuel, a diesel fuel or ECA marine fuel manufacturer must comply with 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 N of this part. A transmix processor 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 § 1090.1020.

(iv) Designate batches of diesel fuel as specified in § 1090.1015.

(d) *Oxygenates.* (1) An oxygenate producer must certify oxygenates intended to be blended into gasoline as specified in paragraph (d)(2) of this section.

(2) To certify batches of oxygenates, an oxygenate producer must comply with 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 § 1090.270 by using the applicable procedures specified in subpart N of this part.

(iii) Assign batch numbers as specified in § 1090.1020.

(iv) Designate batches of oxygenate as intended for blending with gasoline as specified in § 1090.1010(c).

(e) *Certified butane.* (1) A certified butane producer 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, a certified butane producer must comply with all the following:

(i) Ensure that each batch of certified butane meets the requirements in § 1090.250 by using the applicable procedures specified in subpart N of this part.

(A) Testing must occur after the most recent delivery into the certified butane producer's storage tank.

(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 § 1090.1010(d).

(f) *Certified pentane.* (1) A certified pentane producer 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, a certified pentane producer must comply with 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 § 1090.255 by using the applicable

procedures specified in subpart N 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 § 1090.1020.

(iv) Designate batches of certified pentane as intended for blending with gasoline as specified in § 1090.1010(d).

(g) *Certified ethanol denaturant.* (1) A certified ethanol denaturant producer must certify certified ethanol denaturant intended to be used to make DFE that meets the requirements in § 1090.275 as specified in paragraph (g)(2) of this section.

(2) To certify batches of certified ethanol denaturant, a certified ethanol denaturant producer must comply with 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 § 1090.275 by using the applicable procedures specified in subpart N of this part.

(iii) Assign batch numbers as specified in § 1090.1020.

(iv) Designate batches of certified ethanol denaturant as intended for blending with gasoline as specified in § 1090.1010(e).

§ 1090.1005 Designation of batches of fuels, fuel additives, and regulated blendstocks.

(a) A fuel manufacturer, fuel additive manufacturer, or regulated blendstock producer must designate batches of fuel, fuel additive, or regulated blendstock as specified in this subpart.

(b) A fuel manufacturer, fuel additive manufacturer, or regulated blendstock producer must designate the fuel, fuel additive, or regulated blendstock prior to the fuel, fuel additive, or regulated blendstock leaving the facility where it was produced and must include the designations on PTDs as specified in this subpart.

(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.

§ 1090.1010 Designation requirements for gasoline and regulated blendstocks.

(a) *Designation requirements for gasoline manufacturers.* A gasoline manufacturer must accurately and clearly designate each batch of gasoline as follows:

(1) A gasoline manufacturer must designate each batch of gasoline as one of the following fuel types:

(i) Winter RFG.

(ii) Summer RFG.

(iii) Winter RBOB.

(iv) Summer RBOB.

(v) Winter CG.

(vi) Summer CG.

(vii) Winter CBOB.

(viii) Summer CBOB.

(ix) Exempt gasoline under subpart G of this part (including additional identifying information).

(x) California gasoline.

(2) A gasoline manufacturer must further designate gasoline designated as Summer CG or Summer CBOB as follows:

(i) 7.8 psi Summer CG or Summer CBOB, respectively.

(ii) 9.0 psi Summer CG or Summer CBOB, respectively.

(iii) SIP-controlled Summer CG or Summer CBOB, respectively.

(3) A CBOB or RBOB manufacturer 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(a)(5).

(4) In addition to any other applicable designation in this paragraph (a), gasoline designed for downstream oxygenate blending for which the gasoline manufacturer has not accounted for oxygenate added downstream under § 1090.710 must be designated as ''Intended for Oxygenate Blending'', along with a designation indicating the type(s) and amount(s) of oxygenate to be blended with the gasoline.

(b) *Designation requirements for gasoline distributors and certain gasoline blending manufacturers.* A gasoline distributor, certified butane blender, certified pentane blender, or party that recertifies BOB under § 1090.740 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) A distributor must accurately and clearly classify each batch or portion of a batch of gasoline as specified by the gasoline manufacturer in paragraph (a) of this section.

(2) Except as specified in paragraph (b)(2)(vii) of this section, a distributor, certified butane blender, certified pentane blender, or party that recertifies BOB under § 1090.740 may redesignate a batch or portion of a batch of gasoline without recertifying the batch or portion of a batch as follows:

(i) Winter RFG or Winter RBOB may be redesignated as either Winter CG or Winter CBOB.

(ii) Winter CG or Winter CBOB may be redesignated as either Winter RFG or Winter RBOB.

(iii) Summer RFG, Summer RBOB, Summer CG, or Summer CBOB may be redesignated without recertification 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, Summer RBOB, Summer CG, or Summer CBOB may be redesignated without recertification as either Winter RFG, Winter RBOB, Winter CG, or Winter CBOB.

(v) Summer CG, Summer CBOB, or any winter gasoline may be redesignated to either Summer RFG or Summer RBOB, provided the RVP is determined using the applicable procedures specified in subpart N of this part and the new batch meets the RFG RVP standard specified in § 1090.215(a)(3).

(vi)(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)(vi)(A) of this section may instead be recertified as gasoline under § 1090.1000(b).

(vii) CG or RFG must not be redesignated as BOB.

(3) A distributor, certified butane blender, certified pentane blender, or party that recertifies BOB under § 1090.740 that redesignates a batch or portion of a batch 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.* An oxygenate producer 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.* A certified butane or certified pentane producer must accurately and clearly designate each batch of certified butane or certified pentane as one of the following types:

(1) Certified butane.

(2) Certified pentane.

(e) *Designation requirements for certified ethanol denaturant.* A certified ethanol denaturant producer must accurately and clearly designate batches of certified ethanol denaturant as ''certified ethanol denaturant''.

(f) *Designation requirements for TGP.* A transmix processor must accurately and clearly designate any TGP that they transfer to any other person as ''TGP''.

§ 1090.1015 Designation requirements for diesel and distillate fuels.

(a) *Designation requirements for diesel and distillate fuel manufacturers.* (1) Except as specified in paragraph (a)(3) of this section, a diesel fuel or distillate fuel manufacturer must accurately and clearly designate each batch of diesel fuel or distillate fuel as at least one of the following fuel types:

(i) ULSD. A diesel fuel manufacturer may also designate ULSD as 15 ppm MVNRLM diesel fuel.

(ii) 500 ppm LM diesel fuel.

(iii) Heating oil.

(iv) Jet fuel.

(v) Kerosene.

(vi) ECA marine fuel.

(vii) Distillate global marine fuel.

(viii) Certified NTDF.

(ix) Exempt diesel fuel or distillate fuel under subpart G of this part (including additional identifying information).

(2) Only a fuel manufacturer that complies with the requirements in § 1090.515 may designate fuel as 500 ppm LM diesel fuel.

(3) Any batch of diesel fuel or distillate fuel that is certified and designated as ULSD may also be designated as heating oil, kerosene, ECA marine fuel, jet fuel, or distillate global marine fuel if it is also suitable for such use.

(b) *Designation requirements for distributors of diesel and distillate fuels.* A distributor of diesel and distillate fuels must accurately and clearly designate each batch of diesel fuel or distillate fuel for which they transfer custody as follows:

(1) A distributor must accurately and clearly designate such diesel fuel or distillate fuel by sulfur content while it is in their custody (*e.g.,* as 15 ppm or 500 ppm).

(2) A distributor must accurately and clearly designate such diesel fuel or distillate fuel as specified by the diesel fuel or distillate fuel manufacturer under paragraph (a) of this section.

(3) A distributor may redesignate batches or portions of batches of diesel fuel 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 500 ppm LM diesel fuel, heating oil, kerosene, ECA marine fuel, jet 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, ECA marine fuel, or jet fuel may be redesignated as ULSD if the fuel meets the ULSD standards in § 1090.305 and was designated as ULSD under paragraph (a) of this section.

(v) 500 ppm LM diesel fuel may be redesignated as ECA marine fuel, distillate global marine fuel, or heating oil. 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 § 1090.1115) to demonstrate compliance with the 500 ppm sulfur standard in § 1090.320(b).

(vi) Fuel designated as certified NTDF may be redesignated as ULSD without recertification if the applicable requirements of 40 CFR 80.1408 are met.

(c) *ULSD designation limitation.* No person may designate distillate fuel with a sulfur content greater than the sulfur standard in § 1090.305(b) as ULSD.

§ 1090.1020 Batch numbering.

(a) A fuel manufacturer, fuel additive manufacturer, or regulated blendstock producer 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.

(c) A gasoline manufacturer that recertifies BOBs under § 1090.740 may include up to a single month's volume as a single batch for purposes of reporting to EPA.

Subpart L—Product Transfer Documents

§ 1090.1100 General requirements.

(a) *General provisions.* (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 to the ultimate end user at a retail outlet or WPC facility, the transferor must provide the transferee PTDs that include 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.

(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 § 1090.1010 or distillate-related products specified in § 1090.1015.

(b) *Use of codes.* Except for transfers to a truck carrier, retailer, or WPC, product codes may be used to convey the information required under this subpart, if such codes are clearly understood by each transferee.

(c) *Part 80 PTD requirements.* For fuel, fuel additive, or regulated blendstock subject to 40 CFR part 80, subpart M, a party must also include the applicable PTD information required under 40 CFR 80.1453.

§ 1090.1105 PTD requirements for exempt fuels.

(a) In addition to the information required under § 1090.1100, on each occasion when any person transfers custody or title to any exempt fuel

under subpart G of this part, other than when fuel is sold or dispensed to the ultimate end user at a retail outlet or WPC facility, the transferor must provide 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''.

§ 1090.1110 PTD requirements for gasoline, gasoline additives, and gasoline regulated blendstocks.

(a) *General requirements.* On each occasion when any person transfers custody or title of any gasoline, gasoline additive, or gasoline regulated blendstock, other than when fuel is sold or dispensed to the ultimate end user at a retail outlet or WPC facility, the transferor must provide the transferee PTDs that include the following information:

(1) All applicable information required under § 1090.1100 and this section.

(2) An accurate and clear statement of the applicable designation of the gasoline, gasoline additive, or gasoline regulated blendstock under § 1090.1010.

(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) for which the BOB was certified under § 1090.710(a)(5).

(2) *Summer BOB language requirements.* (i) Except as specified in paragraph (b)(2)(ii) 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:

(A) ''9.0 psi CBOB. This product does not meet the requirements for summer reformulated gasoline.''

(B) ''7.8 psi CBOB. This product does not meet the requirements for summer reformulated gasoline.''

(C) ''RBOB. This product meets the requirements for summer reformulated or conventional gasoline.''

(ii) For BOBs designed to produce a finished gasoline that must meet an RVP 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)(1): ''9.0 psi Gasoline.''

(B) For gasoline that meets the 7.8 psi RVP standard in § 1090.215(a)(2): ''7.8 psi Gasoline.''

(C) For gasoline that meets the RFG 7.4 psi RVP standard in § 1090.215(a)(3): ''Reformulated Gasoline.''

(ii) For finished gasoline that meets an RVP 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 between 10 and 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 § 1090.260.

(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 in § 1090.265(a), the transferor must provide to the transferee PTDs that include 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 in § 1090.275, the transferor must provide to the transferee PTDs that include 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, for the certified pentane producer, the 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 must be transferred from each party transferring certified butane or certified pentane for use by a certified butane or certified pentane blender to each party that receives the certified butane or certified pentane through to the certified butane or certified pentane blender, respectively.

(i) *TGP language requirements.* In addition to any other PTD requirements of this subpart, on each occasion when any person transfers custody or title to any TGP, the transferor must provide to the transferee PTDs that include the following information:

(1) The following statement: ''Transmix Gasoline Product—not for use as gasoline.''

(2) [Reserved]

§ 1090.1115 PTD requirements for distillate and residual fuels.

(a) *General requirements.* On each occasion when any person transfers custody or title of any distillate or residual fuel, other than when fuel is sold or dispensed to the ultimate end user at a retail outlet or WPC facility, 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 § 1090.1015 (*e.g.,* ''ULSD'', ''500 ppm LM diesel fuel'', or ''ECA marine fuel'').

(3) If the fuel does not meet the sulfur standard in § 1090.305(b) for ULSD, 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, PTDs must include the following information:

(1) The following statement: ''500 ppm sulfur (maximum) LM diesel fuel. For use only in accordance with a compliance plan under 40 CFR 1090.515(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, PTDs must include the following information:

(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) A party 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, a fuel supplier (*i.e.,* the person who transfers custody or title of marine fuel onto a vessel) must provide bunker delivery notes to vessel operators.

(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, PTDs must include the following information:

(1) The following statement: ''5,000 ppm sulfur (maximum) Distillate Global Marine Fuel. For use only in steamships or Category 3 marine vessels outside of an Emission Control Area (ECA), consistent with MARPOL Annex VI.''

(2) [Reserved]

§ 1090.1120 PTD requirements for diesel fuel additives.

In addition to any other PTD requirements in this subpart, on each occasion when 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), 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 in § 1090.310(b), the transferor must provide to the transferee PTDs that identify the additive as such, and comply with 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 content 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.''

§ 1090.1125 Alternative PTD language.

(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 M—Recordkeeping

§ 1090.1200 General recordkeeping requirements.

(a) *Length of time records must be kept.* Records required under 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) *PTDs.* Any party that transfers custody or title of any fuel, fuel additive, or regulated blendstock must maintain the PTDs for which the party is the transferor or transferee.

(c) *Sampling and testing.* Any party that performs any sampling and testing on any fuel, fuel additive, or regulated blendstock must keep records of the following information:

(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, all the results must be retained.

(4) The methodology used for any testing 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) Records demonstrating the actions taken to stop the sale of any fuel, fuel additive, or regulated blendstock that is 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) *Registration.* Any party required to register under subpart I of this part 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) *Reporting.* Any party required to submit reports under subpart J of this part 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) *Exemptions.* Any party that produces or distributes exempt fuel, fuel additive, or regulated blendstock under subpart G of this part must keep the following records:

(1) Records demonstrating the 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 exempt 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, a gasoline manufacturer must keep records for each of their facilities that include the information in this section.

(b) *Batch records.* For each batch of gasoline, a gasoline manufacturer 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 N 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 § 1090.1010.

(6) The PTDs for any gasoline produced or imported.

(7) The PTDs for any gasoline received.

(c) *Downstream oxygenate accounting.* For BOB for which the gasoline manufacturer has accounted for oxygenate added downstream under § 1090.710, a gasoline manufacturer 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 NFSP under § 1090.1405.

(3) Records that demonstrate that the gasoline manufacturer participates in the NSTOP under § 1090.1450.

(4) Compliance calculations specified in § 1090.700 based on an assumed addition of oxygenate.

(d) *PCG and TGP.* For new batches of gasoline produced by adding blendstock to PCG or TGP, a gasoline manufacturer must keep records of the following information:

(1) Records that reflect the storage and movement of the PCG or TGP and blendstock within the fuel manufacturing facility to the point such

PCG or TGP is used to produce gasoline or BOB.

(2) For new batches of gasoline produced by adding blendstock to PCG or TGP under § 1090.1320(a)(1) or § 1090.1325, respectively, keep records of the following additional information:

(i) The results of tests to determine the sulfur content, benzene content, oxygenate(s) content, and in the summer, RVP, for the PCG or TGP and volume of the PCG or TGP when received at the fuel manufacturing facility.

(ii) Records demonstrating which specific batches of PCG or TGP were used in each new batch of gasoline.

(iii) Records demonstrating which blendstocks were used in each new batch of gasoline.

(iv) Records of the test results for sulfur content, benzene content, oxygenate(s) content, distillation parameters, and in the summer, RVP, for each new batch of gasoline.

(3) For new batches of gasoline produced by adding blendstock to PCG or TGP under § 1090.1320(a)(2), keep records of the following additional information:

(i) Records of the test results for sulfur content, benzene content, oxygenate(s) content, and in the summer, RVP, of each blendstock used to produce the new batch of gasoline.

(ii) Records of the test results for sulfur content and in the summer, RVP, of each new batch of gasoline.

(iii) Records demonstrating which blendstocks were used in each new batch of gasoline.

(e) *Certified butane and certified pentane blenders.* For certified butane or certified pentane blended into gasoline or BOB under § 1090.1320, a certified butane or certified pentane blender must keep records of the following information:

(1) The volume of certified butane or certified pentane added.

(2) The purity and properties of the certified butane or certified pentane specified in § 1090.250 or § 1090.255, respectively.

(f) *Importation of gasoline treated as blendstock.* For any imported GTAB, an importer 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 or the point at which the GTAB was certified as gasoline.

(g) *ABT.* A gasoline manufacturer 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 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, ECA marine fuel, and distillate global marine fuel manufacturers.

(a) *Overview.* In addition to the requirements in § 1090.1205, a diesel fuel or ECA marine fuel manufacturer 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, a diesel fuel or ECA marine fuel manufacturer 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 § 1090.1015.

(5) All documents and information created or used for the purpose of batch designation under § 1090.1015, including PTDs for the batch.

(c) *Distillate global marine fuel manufacturers.* For distillate global marine fuel, a distillate global marine fuel manufacturer must keep records of the following information:

(1) The designation of the fuel as distillate global marine fuel.

(2) The PTD for the distillate global marine fuel.

§ 1090.1220 Recordkeeping requirements for oxygenate blenders.

(a) *Overview.* In addition to the requirements in § 1090.1205, an oxygenate blender that blends oxygenate into gasoline must keep records that include the information in this section.

(b) *Oxygenate blenders.* For each occasion that an oxygenate blender blends oxygenate into gasoline, the oxygenate blender 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 manufacturers.* In addition to the requirements in § 1090.1205, a gasoline additive manufacturer 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) *Parties that take custody of gasoline additives.* 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 gasoline additive blender 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 each case 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, an oxygenate producer 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 of paragraph (a) of this section, a DFE producer 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) *Parties that take custody of oxygenate.* All parties that take custody of oxygenate—from the oxygenate producer through to the oxygenate blender—must keep records of the following information:

(1) The PTD for each batch of oxygenate.

(2) [Reserved]

§ 1090.1235 Recordkeeping requirements for ethanol denaturant.

(a) *Certified ethanol denaturant producers.* In addition to the requirements in § 1090.1205, a certified ethanol denaturant producer 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 § 1090.270(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, a gasoline detergent blender must keep records that include the information in this section.

(b) *Gasoline detergent blenders.* A gasoline detergent blender must keep records of the following information:

(1) The PTD for each detergent used.

(2) For an automated detergent blending facility, 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 a facility that uses 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 a facility that uses 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 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 a non-automated detergent blending facility, keep records of the following information:

(i) The date of additization.

(ii) The volume of detergent added.

(iii) The volume of gasoline to which the detergent was added.

(iv) The actual detergent concentration, calculated as the volume of detergent added (per paragraph (b)(3)(ii) of this section) divided by the volume of gasoline (per 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) *Overview.* In addition to the requirements in § 1090.1205, an independent surveyor must keep records that include the information in this section.

(b) *Independent surveyors.* An independent surveyor must keep records of the following information, as applicable:

(1) Records related to the NFSP under § 1090.1405.

(2) Records related to a geographically-focused E15 survey program under § 1090.1420(b).

(3) Records related to the NSTOP under § 1090.1450.

§ 1090.1250 Recordkeeping requirements for auditors.

(a) *Overview.* In addition to the requirements in § 1090.1205, an auditor must keep records that include the information in this section.

(b) *Auditors.* An auditor must keep records of the following information:

(1) Documents pertaining to the performance of each audit performed under subpart S of this part, including all correspondence between the auditor and the fuel manufacturer.

(2) Copies of each attestation report prepared and all related records developed to prepare the attestation report.

§ 1090.1255 Recordkeeping requirements for transmix processors, transmix blenders, transmix distributors, and pipeline operators.

(a) *Overview.* In addition to the requirements in § 1090.1205, a transmix processor, transmix blender, transmix distributor, or pipeline operator must keep records that include the information in this section.

(b) *Transmix.* (1) A transmix processor or transmix distributor must keep records that reflect the results of any sampling and testing required under subpart F or M of this part.

(2) A transmix processor 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 § 1090.505.

(3) A transmix processor that adds blendstock to TGP or PCG must keep records under § 1090.1210(d).

(4) A transmix blender must keep records showing compliance with the quality assurance program and/or sampling and testing requirements in § 1090.500, 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.

(c) *500 ppm LM diesel fuel.* A manufacturer or distributor 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 § 1090.515(g).

(2) Documents demonstrating how the party complies with each applicable element of the compliance plan under § 1090.515(g).

(3) Documents and copies of calculations used to determine compliance with the 500 ppm LM diesel fuel volume requirements under § 1090.515(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.

(d) *Pipeline operators.* A pipeline operator must keep records that demonstrate compliance with the interface handling practices in § 1090.520.

Subpart N—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 a 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 acting on behalf of a regulated party to demonstrate compliance with requirements under this part must meet the requirements of this subpart in the same way that the party needs to meet those requirements for its own testing. The regulated party and the third party will both be liable for any violations arising from the third party's failure to meet the requirements of this subpart.

(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 Q of this part has provisions related to importation, including additional provisions that specify how to meet the sampling and testing requirements of this subpart.

Scope of Testing

§ 1090.1310 Testing to demonstrate compliance with standards.

(a) Perform testing as needed to certify fuel, fuel additive, or regulated blendstock as specified in subpart K of this part. This section specifies additional test requirements.

(b) A fuel manufacturer, fuel additive manufacturer, or regulated blendstock producer must perform the following measurements before fuel, fuel additive, or regulated blendstock from a given batch leaves the 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 standards and perform testing for each batch of summer gasoline to demonstrate compliance with RVP standards.

(c) The following testing provisions apply for gasoline, oxygenate, certified ethanol denaturant, certified butane, and certified pentane:

(1) A gasoline manufacturer producing BOB for which oxygenate added downstream is accounted for under § 1090.710 must prepare a hand blend as specified in § 1090.1340 and perform the following measurements:

(i) Measure the sulfur content of both the BOB and the hand blend.

(ii) Except as specified in § 1090.1325(c), measure the benzene content of the hand blend.

(iii) For Summer CG, measure the RVP of the BOB.

(iv) For Summer RFG, measure the RVP of the hand blend.

(2) A gasoline manufacturer producing gasoline for which oxygenate added downstream is not accounted for under § 1090.710 (*e.g.,* E0 or so-called suboctane gasoline) must perform the following measurements:

(i) Measure the sulfur content of the gasoline.

(ii) Except as specified in § 1090.1325(c), measure the benzene content of the gasoline.

(iii) For Summer CG and Summer RFG, measure the RVP of the gasoline.

(iv) For Summer RFG that is designated as ''Intended for Oxygenate Blending'' under § 1090.1010(a)(4), create a hand blend as specified in § 1090.1340 and measure the RVP of the hand blend.

(v) For gasoline blended with oxygenate, measure the oxygenate content of the gasoline.

(3) An oxygenate producer must measure the sulfur content of each batch of oxygenate, except that a DFE producer may meet the alternative requirements in § 1090.1330.

(4) An ethanol denaturant producer that certifies denaturant under § 1090.1330 must measure the sulfur content of each batch of denaturant.

(5) A certified butane or certified pentane producer must perform sampling and testing to demonstrate compliance with purity specifications and sulfur and benzene standards as specified in § 1090.1320.

(6) A transmix processor producing gasoline from TGP must test each batch of gasoline for parameters required to demonstrate compliance with § 1090.505 as specified in § 1090.1325.

(d) A blending manufacturer 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, a gasoline manufacturer must measure such gasoline for oxygenate and for distillation parameters (*i.e.,* T10, T50, T90, final boiling point, and percent residue). However, a fuel manufacturer or transmix processor does not need to measure the oxygenate content of gasoline if PCG, transmix, TGP, and blendstocks used to produce the batch did not contain any oxygenates, based on the following documentation:

(1) For PCG, documentation consists of oxygenate content identified on PTDs.

(2) For transmix, TGP, and blendstocks, documentation consists of affidavits or oxygenate test results from the person providing the transmix or blendstock stating that these products do not contain oxygenate.

§ 1090.1315 In-line blending.

A fuel manufacturer 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) 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 it 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. Describe clearly which portions of your blending operation are the subject of your waiver request.

(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. Also describe how your procedures 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. Explain how you will ensure that all fuel will meet all applicable per-gallon standards. Describe any experiences from the previous 3 years where these quality assurance procedures led you to make corrections to your in-line blending operation. Describe how you will deal with release of fuel that fails to meet a per-gallon standard.

(5) Describe any times from the previous 3 years that you modified fuel after it left your facility. Describe how you modified the fuel and why that was necessary.

(6) Describe how you will meet the auditing requirements specified in § 1090.1850 and any additional, facility-specific considerations that relate to those auditing requirements.

(b) You must arrange for an audit of your blending operation each calendar year as specified in § 1090.1850. The audit must review procedures and documents to determine whether measured and calculated values properly represent the aggregate fuel properties for the blended fuel.

(c) You must submit an updated in-line blending waiver request to EPA 60 days before making any material change to your in-line blending process. Examples of material changes include changing analyzer hardware or programming, changing the location of the analyzer, changing the piping configuration, changing the mixing control hardware or programming logic, changing sample compositors or compositor settings, or expanding fuel blending capacity. Changing the name of the company or business unit is an example of a change that is not material.

(d) 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 a refiner or blending manufacturer that adds blendstock to PCG to produce a new batch of gasoline.

Paragraph (b) of this section specifies an alternative approach for a certified butane or certified pentane blender. Section 1090.1325 describes additional provisions that apply to a transmix processor.

(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) Determine the sulfur content, benzene content, and oxygenate content of the PCG before blending blendstocks to produce a new batch of gasoline as follows:

(A) Sample and test the sulfur content, benzene content, and oxygenate content of each batch of PCG. The blending manufacturer does not need to test PCG for oxygenate content if they can demonstrate that the PCG does not contain oxygenates as specified in paragraph (a)(1)(i)(C) of this section or § 1090.1310(e)(1).

(B) If the PCG is a BOB, prepare a hand blend under § 1090.1340 and test the hand blend for sulfur content and benzene content.

(C) The blending manufacturer may use the PCG manufacturer's certification test results if the PCG was received directly from the PCG manufacturer by an in-tank transfer or tank-to-tank transfer within the same terminal as long as the results are from the PCG that is being transferred.

(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 content, benzene content, and for summer gasoline, RVP, 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 content and benzene content of each batch of blendstock used to produce a new batch of gasoline from PCG using the procedures in § 1090.1350. The homogeneity requirements for gasoline specified in § 1090.1337 apply to blendstock and GTAB collected with manual sampling.

(ii) Determine the volume of each batch of blendstock used to produce the new batch of gasoline.

(iii) Determine the volume of each blended batch of gasoline, and measure the sulfur content and for summer gasoline, RVP, for each blended batch of gasoline using the procedures specified in § 1090.1350. Testing the blended batch of gasoline for sulfur content, however, is not required if the fuel manufacturer tests the added blendstock and determines that both the blendstock and PCG meet the fuel manufacturing facility gate sulfur per-gallon standard in § 1090.205(b).

(iv) Report each batch of blendstock as specified in § 1090.905(c)(4).

(v) Include each batch of blendstock in compliance calculations as specified in § 1090.700(d)(4)(ii).

(vi) The sample retention requirements in § 1090.1345 apply for the new batch of gasoline and for each blendstock.

(b) A certified butane or certified pentane blender that blends 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 paragraph (a) 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 § 1090.220(e) disallows adding certified butane or certified pentane to Summer RFG or Summer RBOB.

(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 § 1090.250 or § 1090.255, 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 § 1090.250 or § 1090.255, 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 distributor. The certified butane or certified pentane blender may rely on a third party to perform the testing.

(c) This paragraph describes provisions that apply in cases where PCG is a BOB for which the PCG manufacturer accounted for oxygenate added downstream under § 1090.710 and the blending manufacturer makes a new batch that includes less oxygenate than was specified for the BOB by the PCG manufacturer. A blending manufacturer in this circumstance does not qualify for the small volume blender exemption for BOB recertification under § 1090.740(a)(3) and must comply with all the following.

(1) Calculate and incur sulfur and benzene deficits under the BOB recertification provisions in § 1090.740.

(2) Comply with either the compliance by subtraction requirements of paragraph (a)(1) of this section or the compliance by addition requirements of paragraph (a)(2) of this section. For compliance by subtraction, test the PCG without adding oxygenate (*i.e.,* test the PCG ''neat''), and report the PCG volume without adjusting for the volume of oxygenate that the PCG manufacturer specified under § 1090.740.

§ 1090.1325 Adding blendstock or PCG to TGP.

The following provisions apply to a transmix processor or blending manufacturer producing gasoline by adding blendstock or PCG to TGP:

(a) 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.

(b) Sample and test the gasoline made from TGP and PCG or blendstock to demonstrate compliance with the fuel manufacturing facility gate sulfur per-gallon standard in § 1090.205(b) and the applicable RVP standard in § 1090.215.

(c) A transmix processor producing gasoline by only adding TGP to PCG does not have to measure the benzene content of the finished gasoline.

§ 1090.1330 Preparing denatured fuel ethanol.

Instead of measuring every batch, a DFE producer or importer 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, preparing, and testing samples.

(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. A description of how to determine compliance based on single or multiple tests on single or multiple samples is specified in paragraph (e) of this section.

(b) *Manual sampling.* Perform manual sampling using one of the methods specified in ASTM D4057 (incorporated by reference in § 1090.95) to demonstrate compliance with standards as follows:

(1) 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.

(2)(i) Use tap sampling or spot sampling to collect upper, middle, and lower samples if a running or all-levels sample is impractical for a given storage configuration. Collect samples that most closely match the recommendations in Table 5 of ASTM D4057. Adjust spot sampling for partially filled tanks as shown in Table 1 or Table 5 of ASTM D4057, as applicable.

(ii) Spot sampling must not be used for certification testing unless the tank contains less than 10 feet of product.

(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.

(5) Except as specified for marine vessels in § 1090.1605, you must not do certification testing with a composite sample from manual sampling.

(c) *Automatic sampling.* (1) For in-line blending waivers under § 1090.1315, follow all specifications for automatic sampling as specified in EPA's approval letter instead of or in addition to the specifications in paragraph (c)(2) of this section. Automatic sampling is also appropriate for a configuration involving a pipeline filling a tank that will be certified as compliant before it leaves the fuel manufacturing facility gate.

(2) Perform automatic sampling as specified in ASTM D4177 (incorporated by reference in § 1090.95), with the following additional specifications:

(i) Configure the system to ensure a well-mixed stream at the sampling point. Align the start and end of sampling with the start and end of creating the batch.

(ii) The default sampling frequency must follow the recommended approach of at least 9,604 samples to represent a batch. Less frequent sampling is acceptable as long as the interval between samples does not exceed 20 seconds throughout the batch.

(iii) Collect three samples for individual measurements in addition to the composite sample. Draw head, middle, and tail samples after flowing 15, 50, and 85 percent of the estimated batch volume, respectively.

(iv) EPA may approve a different sampling strategy under an approved in-line blending waiver under § 1090.1315 if it is appropriate for a given facility or for a small-volume 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 other fuel parameters for a given sample in addition to RVP testing, always measure RVP first.

(e) *Testing to demonstrate compliance with standards.* (1) Perform testing as specified in this subpart.

(2) For parameters subject to per-gallon standards, report the highest measured value (or the lowest measured value for testing related to cetane index or other parameters that are subject to a standard representing a minimum value). This applies for repeat tests on a given sample and for testing multiple samples (including head, middle, and tail samples from automatic sampling). A batch is noncompliant if any tested sample does not meet all applicable per-gallon standards.

(3) In the case of automatic sampling for parameters subject to average standards, report the result from the composite sample to represent the batch for demonstrating compliance with the average standard. For any repeat testing with the composite sample, calculate the arithmetic average from all tests to represent the batch.

(4) In the case of manual sampling for parameters subject to average standards, determine the value representing the batch as follows:

(i) For testing with only a single sample, report that value to represent the batch. If there are repeat tests with that sample, report the arithmetic average from all tests to represent the sample.

(ii) For testing with more than one sample, report the arithmetic average from all tested samples to represent the batch. If there are repeat tests for any sample, calculate the arithmetic average of those repeat tests to determine a single value to represent that sample before calculating the average value to represent the batch.

§ 1090.1337 Demonstrating homogeneity.

(a) Certification test results corresponding to manual sampling as specified in § 1090.1335(b) are valid only if collected samples meet the homogeneity specifications in this section, except that the homogeneity testing requirement does not apply in the following cases:

(1) There is only a single sample using the procedure specified in § 1090.1335(b)(2).

(2) Upright cylindrical tanks that have a liquid depth of less than 10 feet.

(3) You draw spot or tap samples as specified in paragraph (c) of this section, 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.

(4) Sampling at a downstream location where it is not possible to collect separate samples and steps are taken to ensure that the batch is well mixed.

(b)(1) Testing performed to establish homogeneity is not considered certification testing, except as specified in paragraph (b)(2) of this section.

(2) Homogeneity testing may be used as certification testing if any of the following criteria are met:

(i) All tested samples meet all applicable per-gallon standards.

(ii) The testing meets the requirement in § 1090.1335(b)(2)(ii).

(iii) The testing follows the procedures specified in paragraph (a)(3) of this section.

(c) Use spot sampling as specified in § 1090.1335(b)(2) for homogeneity testing. Tap sampling is acceptable if spot sampling is impractical for a given facility.

(d) Demonstrate homogeneity for gasoline using two of the procedures specified in this paragraph (d) with each sample. For summer gasoline, the homogeneity demonstration must include RVP measurement.

(1) Measure API gravity using ASTM D287, ASTM D1298, ASTM D4052, or ASTM D7777 (incorporated by reference in § 1090.95).

(2) Measure the sulfur content as specified in § 1090.1360.

(3) Measure the benzene content as specified § 1090.1360.

(4) Measure the RVP as specified in § 1090.1360.

(e) For testing to meet the diesel fuel standards in subpart D of this part, demonstrate homogeneity using one of the procedures specified in paragraph (d)(1) or (2) of this section.

(f) Consider the batch to be homogeneous for a given parameter if the measured values for all tested samples vary by less than the published reproducibility of the test method multiplied by 0.75 ($R \times 0.75$). If reproducibility is a function of measured values, calculate reproducibility 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 paragraph (a) of this section, 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 requirements of this subpart by blending oxygenate that reflects the anticipated sulfur content and benzene content of the oxygenate for blending into a BOB sample. To do this, prepare each hand blend 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 as follows:

(1) Take steps to avoid introducing high or low bias in sulfur content when selecting from available samples to prepare 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 a downstream blender to add more than one type or concentration of oxygenate, prepare the hand blend as follows:

(i) For summer gasoline intended for blending with ethanol, use the lowest specified ethanol blend.

(ii) For all winter gasoline and for summer gasoline intended for blending only with oxygenate other than ethanol, use the lowest specified oxygenate concentration, regardless of the type of oxygenate.

(iii) As an 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) Prepare the hand blend using the procedures specified in ASTM D7717 (incorporated by reference in § 1090.95). The hand blend must have an amount of oxygenate that does not exceed the oxygenate concentration specified on the PTD for the BOB under § 1090.1110(b)(1).

§ 1090.1345 Retaining samples.

(a) Retain samples as follows:

(1) A fuel manufacturer, regulated blendstock producer, or independent surveyor must keep representative samples of gasoline, diesel fuel, or oxygenate that is subject to certification testing requirements under this subpart for at least 30 days after testing is complete, except that a longer sample retention of 90 days applies for a blending manufacturer that produces gasoline.

(2) A certified pentane producer must keep representative samples of certified pentane for at least 30 days after testing is complete.

(3) A blending manufacturer required to test blendstock under § 1090.1320(a)(2) must keep representative samples of the blendstock and the new batch of gasoline for at least 90 days after testing is complete.

(4) An oxygenate producer or importer must keep oxygenate samples as follows:

(i) 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.

(ii) 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.

(5) The nominal volume of retained liquid 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 are required to test a hand blend under § 1090.1340, keep a sample of the BOB and a sample representative of the oxygenate used to prepare the hand blend.

(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.

(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.

A fuel manufacturer, fuel additive manufacturer, regulated blendstock producer, or independent surveyor meets 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 that meets ASTM D6751 (incorporated by reference in § 1090.95).

(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. There is no aromatics-related test requirement for biodiesel that meets ASTM D6751.

(3) Measure the purity of butane as specified in ASTM D2163 (incorporated by reference in § 1090.95). Measure the purity of pentane as specified in ASTM D2163 or ASTM D5134 (incorporated by reference in § 1090.95).

(4) Measure the benzene content of butane and pentane as specified in ASTM D2163, ASTM D5134, ASTM D6729, or ASTM D6730 (incorporated by reference in § 1090.95).

(5) Measure the sulfur content of pentane as specified in ASTM D5453 (incorporated by reference in § 1090.95).

(6) Measure distillation parameters 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. You may use an alternative procedure if you adequately 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 O of this part:

TABLE 1 TO PARAGRAPH (b)(11)—ADDITIONAL SURVEY TEST METHODS

Fuel parameter	Units	Test method [1]
Distillation	°C	ASTM D86.
Aromatic content	volume percent	ASTM D5769.
Olefin content	volume percent	ASTM D6550.

[1] ASTM specifications are incorporated by reference, see § 1090.95.

(12) Updated versions of the test procedures specified in this section are acceptable as alternative procedures if both repeatability and reproducibility are the same or better than 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 15.56 °C. 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 as follows:

(a) Adjust measured values for total vapor pressure as follows:

$$\text{RVP (psi)} = 0.956 \cdot P_{total} - 0.347$$

Where:

P_{total} = Measured total vapor pressure, in psi.

(b) For measuring the sulfur content 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 sulfur content of ULSD at a downstream location, subtract 2 ppm from the result.

(d) 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.

(e) If measured content of any oxygenate compound is less than 0.20 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 a laboratory that uses either referee procedures or alternative procedures.

(3) Streamlined requirements for alternative procedures apply for procedures adopted by a voluntary consensus standards body (VCSB). Certification 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 use updated versions of the referee procedures as alternative procedures subject to the limitations of § 1090.1365(a)(2). 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 repeatability and reproducibility compared to the version specified in § 1090.95. If the updated procedure has worse repeatability or reproducibility 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 laboratory, 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 a laboratory that measures 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)—REFEREE PROCEDURES FOR QUALIFYING ALTERNATIVE PROCEDURES

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, see § 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. For referee procedures and for alternative procedures for method-defined fuel parameters that you have qualified for your laboratory, updated versions of those same procedures are qualified without further testing, as long as the 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 laboratory 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 laboratory.

(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 (b). 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 (R2019).
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.x	2.77		ASTM D6667–14 (R2019).
Gasoline	Sulfur		1.5	r = 0.4998.$x^{0.54}$	2.77		ASTM D7039–15a (R2020).
Gasoline	oxygenate		0.3	R = 0.13.$x^{0.83}$	1		ASTM D5599–18.
Gasoline	RVP [3]		0.3	R = 0.40	1	0.12	ASTM D5191–20.
Gasoline	Benzene		0.15	R = 0.221.$x^{0.67}$	1		ASTM D5769–20.

[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, see § 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 this paragraph 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 procedure 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 laboratories 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 (e)(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 (e)(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 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 in § 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 laboratories 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 laboratory that uses the referee procedure 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 laboratory qualifies as a reference installation, that qualification is valid for five years from the qualifying date, consistent with good laboratory practices.

(b) You may 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) You may qualify a reference installation for VCSB or 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 laboratory 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. 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 laboratory 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 laboratory.

(2) If you fail to conduct specified testing, your test instrument 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 instrument 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 instrument and perform testing to show that the test instrument 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 instrument for performing up to 20 tests or 7 days, whichever is less. Include all tests except for testing to meet precision or accuracy requirements.

(2) Perform precision testing using the control-chart procedures in ASTM D6299. If you opt to use procedure 2A (Q-Procedure) or 2B (dynamically updated exponentially weighted moving average), 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.

(3) Use I charts and MR charts as specified in ASTM D6299 to show that the standard deviation for the test instrument 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 (c). For method-defined VCSB procedures, you may meet accuracy requirements as specified in this paragraph (c) 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 instrument 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)(4)—CRITERIA FOR QUALIFYING ALTERNATIVE PROCEDURES

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, see § 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) An automated detergent blending facility 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.

A gasoline detergent manufacturer must perform testing using one of the methods specified in 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 must 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 § 1090.270 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 Test Method.* Use the procedures specified by CARB in Title 13, California Code of Regulations, section 2257 (incorporated by reference in § 1090.95).

(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) *EPA BMW method.* Use the procedures specified in ASTM D5500 (incorporated by reference in § 1090.95), as follows:

(1) Prepare the test fuel with the following specification:

(i) Sulfur—minimum 340 ppm.

(ii) T90—minimum 171 °C.

(iii) Olefins—minimum 11.4 volume percent.

(iv) Aromatics—minimum 31.1 volume percent.

(v) Ethanol—minimum 10 volume percent.

(vi) Sulfur, T90, olefins, and aromatics specifications must be met before adding ethanol.

(vii) Di-tert-butyl disulfide may be added to the test fuel.

(2) The duration of testing may be less than 10,000 miles. Measured deposits must meet the following specified values to qualify the test fuel and establish a detergent's LAC:

(i) Measured deposits for the fuel without detergent must be at least 290 mg per valve on average.

(ii) Measured deposits for the fuel with detergent must be less than 100 mg per valve on average.

(d) *Alternative test methods.* (1) An EPA-approved alternative test method may be used if the alternative test method can be correlated to any of the methods specified in paragraphs (a) through (c) of this section.

(2) Information describing the alternative test method and analysis demonstrating correlation must be submitted for EPA approval as specified in § 1090.10.

Subpart O—Survey Provisions

§ 1090.1400 General provisions.

(a) *Program plan approval process.* (1) A program plan that complies with the requirements in § 1090.1415 or § 1090.1450 must be submitted to EPA no later than October 15 of the year preceding the calendar year in which the program will be conducted.

(2) The program plan must be signed by an RCO of the independent surveyor conducting the program.

(3) The program plan must be submitted as specified in § 1090.10.

(4) EPA will send a letter to the party submitting the program plan that indicates whether EPA approves or disapproves the plan.

(b) *Independent surveyor contract.* (1) 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.

(2) 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.

§ 1090.1405 National fuels survey program.

(a) *Program participation.* (1) A gasoline manufacturer that elects to account for oxygenate added downstream under § 1090.710 must participate in the national fuels survey program (NFSP) specified in this paragraph (b) of this section.

(2) A party required to participate in an E15 survey under § 1090.1420(a) must participate in the NFSP specified in paragraph (b) of this section or a survey program approved by EPA under § 1090.1420(b) or (c).

(3) Other parties may elect to participate in the NFSP for purposes of establishing an affirmative defense against violations of requirements and provisions under this part as specified in § 1090.1720.

(b) *Program requirements.* The NFSP must meet all the following requirements:

(1) 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.

(2) The survey program must be conducted by collecting samples representative 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 NFSP 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 N 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 under § 1090.1415(e)(3), must also be analyzed for aromatics content, olefins content, and distillation parameters.

(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 N 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 downstream sulfur per-gallon 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 quarterly and annual summary reports that include the information specified in § 1090.925(b) and (c), respectively.

(g) Keep records related to the NFSP as specified in § 1090.1245(b)(1).

(h) Submit contracts to EPA as specified in § 1090.1400(b).

(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 program plan design requirements.

The 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 and 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 program 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 program plan, ϕ_0 will be 2.3%. For subsequent survey program 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 NFSP must be approved annually as part of the survey program plan approval process in § 1090.1400(a). 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 crosscheck program for the most recent 12 months prior to submission of the survey program plan.

(g) *Submission.* Survey program plans submitted under this section must be approved annually under § 1090.1400(a).

§ 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 an oxygenate producer that produces or imports DFE, the DFE is deemed as intended for use in E15 unless the oxygenate producer demonstrates that it was not intended for such use. The oxygenate producer 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.* 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 that meets 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 §§ 1090.1405(a) and (b)(2), 1090.1410(c)(2) and (3), and 1090.1415(b), (d)(1), (2), and (4), and (e). In lieu of meeting these 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.* The gasoline manufacturer, oxygenate blender, or oxygenate producer must participate in the NFSP under § 1090.1405.

§ 1090.1450 National sampling and testing oversight program.

(a) *Program participation.* (1) Except for a gasoline manufacturer that has an approved in-line blending waiver under § 1090.1315 that covers all gasoline produced at their facility, a gasoline manufacturer that elects to account for oxygenate added downstream under § 1090.710 must participate in the national sampling and testing oversight program (NSTOP) in this section.

(2) Other gasoline manufacturers may elect to participate in the NSTOP for purposes of establishing an affirmative defense to a violation under § 1090.1720. A gasoline manufacturer that has an approved in-line blending waiver under § 1090.1315 does not need to participate in the NSTOP in order to establish an affirmative defense to a violation under § 1090.1720.

(3) A gasoline manufacturer that elects to participate in the NSTOP 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 that the sample was collected.

(b) *Program requirements.* The NSTOP must meet all the following requirements:

(1) The NSTOP 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 NSTOP must be conducted at each gasoline manufacturing facility from all participating gasoline manufacturers.

(c) *Independent surveyor requirements.* The independent surveyor conducting the NSTOP must meet all the following requirements:

(1) Submit a proposed NSTOP 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. If the fuel manufacturer only produces fuel during either the summer or winter season, obtain at least one sample during the season that the fuel manufacturer produces fuel.

(ii)(A) Observe the gasoline manufacturer collect at least one sample representing each gasoline required under paragraph (c)(2)(i) of this section for each participating gasoline manufacturing facility and evaluate whether the gasoline manufacturer collected representative sample(s) in accordance with applicable sampling procedures specified in § 1090.1335. Immediately notify EPA and the gasoline manufacturer if the applicable sampling procedures are not followed.

(B) 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.

(C) 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. A gasoline manufacturer that refuses to allow the independent surveyor to take portions of collected samples is no longer considered by EPA to be participating in the NSTOP and must not account for oxygenate added downstream under § 1090.710.

(iv) Samples must be retained by the independent surveyor as specified in § 1090.1345(a)(1).

(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 N of this part.

(iv) All analyses must be completed by the EPA-approved laboratory within 10 business days after receipt of the sample.

(v) A gasoline manufacturer must analyze gasoline samples for sulfur content, 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 that exceeds the fuel manufacturing facility gate sulfur per-gallon standard in § 1090.205(b).

(ii) A test result for a gasoline sample yields an RVP 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 notify 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 N of this part.

(7) Provide quarterly reports to EPA that include the information specified in § 1090.925(d).

(8) Keep records related to the NSTOP as specified in § 1090.1245(b)(3).

(9) Submit contracts to EPA as specified in § 1090.1400(b).

(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 Ratio (PR) from Table 2 Guidelines for Action Based on TPI in ASTM D6792 (incorporated by reference in § 1090.95).

(iii) A gasoline manufacturer 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 NSTOP, including sample collection, transportation, storage, and analysis.

(d) *NSTOP plan requirements.* The NSTOP plan specified in paragraph (c)(1) of this section must include, at a minimum, all the following:

(1) *Advance notice of sampling.* The NSTOP plan must include procedures on how to keep the identification of the gasoline manufacturing facilities included in the NSTOP 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 each season they produce fuel. 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 season samples 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 NSTOP plan.

(ii) The minimum number of samples to be included in the NSTOP 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 NSTOP (*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 NSTOP must be approved annually as part of the program plan approval process in § 1090.1400(a). The independent surveyor must include the following information regarding each 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) Records demonstrating the laboratory's performance in a laboratory crosscheck 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 NSTOP 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.* NSTOP plans submitted under this section must be approved annually under § 1090.1400(a).

Subpart P—Retailer and Wholesale Purchaser-Consumer Provisions

§ 1090.1500 Overview.

(a) A retailer or WPC must comply with 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 as the EPA-required label.

(3) The alternative label must be submitted as specified in § 1090.10.

Labeling

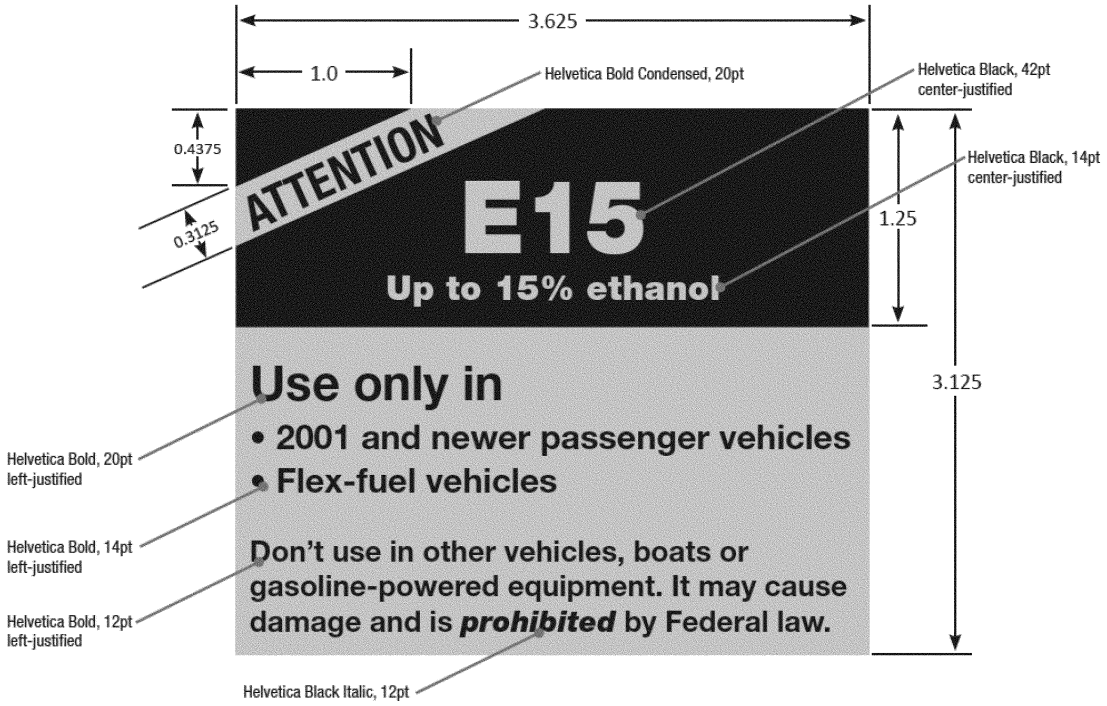
§ 1090.1510 E15 labeling provisions.

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 paragraph 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 to paragraph (b)—E15 Label



§ 1090.1515 Diesel sulfur labeling provisions.

A 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 must 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.

§ 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 that meets the requirements of 40 CFR 86.1813–17(f)(1).

(b) Determine the amount of natural gas vented 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 Q—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)(1) Except as specified in paragraph (b)(2) of this section, all applicable gasoline and diesel standards in subparts C and D of this part apply to imported gasoline and diesel.

(2) A gasoline importer that imports gasoline at multiple import facilities must comply with the gasoline average standards in §§ 1090.205(a) and 1090.210(a) as specified in § 1090.705(b), unless the importer complies with the provisions of § 1090.1610 to meet the alternative per-gallon standards for rail and truck imports specified in §§ 1090.205(d) and 1090.210(c).

(c) An importer must separately comply with any applicable certification or other requirements for U.S. Customs.

(d) Alternative testing requirements for an importer that imports gasoline or diesel fuel by rail or truck are specified in § 1090.1610.

§ 1090.1605 Importation by marine vessel.

An importer that imports fuel, fuel additive, or regulated blendstock using a marine vessel must comply with the requirements of this section.

(a) The importer must certify each fuel, fuel additive, or regulated blendstock imported at each port, unless the fuel is certified at the first port of entry in the United States and then transported by the same vessel to subsequent ports without picking up additional fuel.

(b) Except as specified in paragraph (d) of this section, the importer must certify each fuel, fuel additive, or regulated blendstock while it is on-board the vessel used to transport it to the United States. Certification sampling must be performed after the vessel's arrival at the port where the fuel, fuel additive, or regulated blendstock will be offloaded.

(1) The importer must sample each compartment of the vessel and use one of the following methods to meet testing requirements:

(i) Treat each compartment as a separate batch.

(ii) Combine samples from separate compartments into a single, vessel volumetric composite sample using the procedures in Section 9.2.4 of ASTM D4057 (incorporated by reference in § 1090.95). Test results from the composite sample are valid only after samples are collected from each affected compartment and homogeneity is demonstrated for all samples as specified in § 1090.1337.

(2) The importer must ensure that all applicable per-gallon standards are met before offloading the fuel, fuel additive, or regulated blendstock.

(3) The importer 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 requirements of subpart L of this part.

(d) As an alternative to paragraphs (b) and (c) of this section, the importer may offload fuel, fuel additive, or regulated blendstock into shore tanks that contain the same fuel, fuel additive, or regulated blendstock if the importer meets the following requirements:

(1) For gasoline, the importer must offload gasoline into one or more empty shore tanks or tanks containing PCG that the importer owns.

(i) If the importer offloads gasoline into one or more empty shore tanks, they must sample and test the sulfur content and benzene content, and for summer gasoline, RVP, of each shore tank into which the gasoline was offloaded.

(ii) If the importer offloads 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 content and benzene content, and report this PCG as a negative batch as specified in § 1090.905(c)(3)(i). After offloading the gasoline into the shore tanks, the importer must sample and test the sulfur content, benzene content, and for summer gasoline, RVP, of each shore tank into which the gasoline was offloaded and report the volume, sulfur content, and benzene content as a positive batch.

(iii) Include the PCG in the shore tank before offloading and the volume and properties after offloading in compliance calculations as specified in § 1090.700(d)(4)(i).

(iv) The sample retention requirements in § 1090.1345 apply to the samples taken prior to offloading and those taken after offloading.

(2) For all other fuel, fuel additive, or regulated blendstock, the importer must sample and test the fuel, fuel additive, or regulated blendstock in each shore tank into which it was offloaded. The importer 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.

(a) An importer that imports fuel, fuel additive, or regulated blendstock by rail or truck must meet the sampling and testing requirements of subpart N of this part by sampling and testing each compartment of the truck or railcar unless they do one of the following:

(1) *Use supplier results.* The importer may rely on test results from the supplier for fuel, fuel additive, or regulated blendstock imported by rail or truck if the importer meets all the following requirements:

(i) The importer obtains documentation of test results from the supplier for each batch of fuel, fuel additive, or regulated blendstock in

accordance with the following requirements:

(A) The testing includes measurements for all the fuel parameters specified in § 1090.1310 using the measurement procedures specified in § 1090.1350.

(B) Testing for a given batch occurs 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.

(ii) The importer conducts testing to verify test results from each supplier as follows:

(A) Collect a sample at least once every 30 days or every 50 rail or truckloads from a given supplier, whichever is more frequent. Test the sample as specified in paragraphs (a)(1)(i)(A) and (B) of this section.

(B) 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.

(2) *Certify in a storage tank.* The importer may transfer the fuel, fuel additive, or regulated blendstock imported by rail or truck into storage tanks that also contain the same product if the importer meets the following requirements:

(i) For gasoline, the importer transfers gasoline into one or more empty tanks or tanks containing PCG that the importer owns.

(A) If the importer transfers gasoline into one or more empty tanks, they must sample and test the sulfur content, benzene content, and for summer gasoline, RVP, of each tank into which the gasoline was transferred.

(B) If the importer transfers gasoline into one or more tanks containing PCG, they must sample the PCG already in the tank prior to transferring gasoline from the truck or train, test the sulfur content and benzene content, and report this PCG as a negative batch as specified in § 1090.905(c)(3)(i). After transferring the gasoline into the tanks, the importer must sample and test the sulfur content, benzene content, and for summer gasoline, RVP, of each tank into which the gasoline was transferred and report the volume, sulfur content, and benzene content as a positive batch.

(C) Include the PCG in the tank before transferring and the volume and properties after transferring in compliance calculations as specified in § 1090.700(d)(4)(i).

(D) The sample retention requirements in § 1090.1345 apply to the samples taken prior to transferring and those taken after transferring.

(ii) For all other fuel, fuel additive, or regulated blendstock, the importer must sample and test the fuel, fuel additive, or regulated blendstock in each tank into which it was transferred. The importer must ensure that all applicable per-gallon standards are met before the fuel, fuel additive, or regulated blendstock is shipped from the tank.

(b) If an importer that elects to comply with paragraph (a)(1) or (2) of this section fails to meet the applicable requirements, they must meet the sampling and testing requirements of subpart N of this part for each compartment of the truck or railcar until EPA determines that the importer has adequately addressed the cause of the failure.

§ 1090.1615 Gasoline treated as a blendstock.

(a) An importer may exclude GTAB from their compliance calculations if they meet all the following requirements:

(1) The importer reports the GTAB to EPA under § 1090.905(c)(7).

(2) The 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 the GTAB and must include the gasoline produced using the GTAB in their compliance calculations.

(b) After importation, the title of the GTAB must not be transferred to another party until the GTAB has been either certified as gasoline under subpart K of this part or used to produce gasoline that meets all applicable standards and requirements under this part.

(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 it were imported gasoline and complete all requirements for a gasoline manufacturer under § 1090.105(a) (except for the sampling, testing, and sample retention requirements in § 1090.105(a)(6)) 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, fuel produced, imported, distributed, or offered for sale in the United States is subject to the standards and requirements of this part.

(a) Fuel designated for export by a fuel manufacturer is not subject to the standards in this part, provided all the requirements in § 1090.645 are met.

(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 United States by the U.S. Customs Service under 19 CFR part 10 is not considered to be imported for purposes of this part, provided all the following requirements are met:

(1) The 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) The 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 United States and none may be used in a foreign country.

(4) No fuel classified as American Goods Returned to the United States may be combined with any fuel produced at a foreign fuel manufacturing facility prior to reentry into the United States.

Subpart R—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 under 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 each day of such violation and the amount of economic benefit or savings resulting from the 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 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 day in any compliance period in which invalid credits are generated, transferred, used, or made available for use.

(c)(1) Any person liable under this part for a violation of a per-gallon standard, or for causing another party to violate a per-gallon standard, is subject to a separate day of violation for each 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 day such provision remains unfulfilled.

(e) Failure to meet separate requirements of this part count as separate violations.

(f) Violation of any misfueling prohibition under this part counts as a separate violation for each 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 comply with the sampling or testing requirements and must be reported, unless EPA, in its sole discretion, approves a different value. EPA may consider any relevant information to determine whether a different value is appropriate.

(1) For gasoline: 339 ppm sulfur, 1.64 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: 339 ppm sulfur.

(6) For regulated blendstocks: 339 ppm sulfur and 1.64 volume percent benzene.

§ 1090.1715 Liability provisions.

(a) Any person who violates any prohibited act or 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 any violation of this part that 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.

(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) If 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) A retailer or WPC is 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 the NFSP under § 1090.1405 that was in effect at the time of the violation.

(ii) In addition to the requirements of paragraph (d)(1)(i) of this section, a gasoline manufacturer must also participate in the NSTOP specified in § 1090.1450 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 periodic sampling and testing 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 the 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 oxygenate 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 oxygenate blender, distributor, reseller, carrier, retailer, or WPC 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 oxygenate 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 oxygenate 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 S—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) A gasoline manufacturer that produces or imports gasoline subject to the requirements of subpart C of this part.

(2) A gasoline manufacturer that performs testing as specified in subpart N of this part or that relies on testing from a third-party laboratory.

(b) An auditor performing attestation engagements must meet the following requirements:

(1) The auditor 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. Such an auditor 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 an auditor must comply with the AICPA *Code of Professional Conduct,* including its independence requirements, the AICPA *Statements on Quality Control Standards (SQCS) No. 8, A Firm's System of Quality Control* (both incorporated by reference in § 1090.95), and applicable rules of state boards of public accountancy. Such an auditor 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) An auditor 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 a laboratory 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 a gasoline manufacturer that relies on a third-party laboratory for 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)—SAMPLE SIZE DETERMINATION

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. An auditor that determines 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 for gasoline manufacturers.

An auditor must perform the procedures in this section for a refiner, blending manufacturer, or transmix processer that produces gasoline.

(a) *Registration and EPA reports.* An auditor 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 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 and report 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 and report 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.* An auditor must perform an inventory reconciliation analysis review 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 and report 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.* An auditor 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 and report any variances.

(d) *Listing of batches.* An auditor 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 and report 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.* An auditor 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) *Detailed testing of BOB tenders.* An auditor must review a detailed listing of BOB tenders as follows:

(1) Select a representative sample from the listing of BOB tenders.

(2) Obtain the associated PTD for each selected sample.

(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 and report any exceptions.

(4) Confirm that the PTD associated with each selected BOB tender contains all the applicable language requirements under subpart L of this part and report any exceptions.

(g) *Detailed testing of BOB batches.* An auditor must review a detailed listing of BOB batches as follows:

(1) Select a representative sample from the BOB batch reports submitted under subpart J of this part.

(2) Obtain the volume documentation and laboratory analysis for each selected BOB batch.

(3) Compare the reported volume for each selected BOB batch to the volume documentation and report any exceptions.

(4) Compare the reported properties for each selected BOB batch to the laboratory analysis and report any exceptions.

(5) Compare the reported test methods used for each selected BOB batch to the laboratory analysis and report any exceptions.

(6) Determine each oxygenate type and amount that is required for blending with the BOB.

(7) Confirm that each oxygenate type and amount included in the BOB hand blend agrees with the manufacturer's blending instructions for each selected BOB batch and report any exceptions.

(8) Confirm that the manufacturer participates in the NFSP under § 1090.1405, if applicable.

(9) For a blending manufacturer, confirm that the laboratory analysis includes test results for oxygenate content, if applicable, and distillation parameters (*i.e.,* T10, T50, T90, final boiling point, and percent residue). For a blending manufacturer not required to measure oxygenate content, confirm that records demonstrate that the PCG or blendstock contained no oxygenate, no oxygenate was added to the final gasoline batch, and the blending manufacturer did not account for oxygenate added downstream under § 1090.710.

(h) *Detailed testing of finished gasoline tenders.* An auditor must review a detailed listing of finished gasoline tenders as follows:

(1) Select a representative sample from the listing of finished gasoline tenders.

(2) Obtain the associated PTD for each selected sample.

(3) 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 and report any exceptions.

(4) Confirm that the PTD associated with each selected finished gasoline tender contains all the applicable language requirements under subpart L of this part and report any exceptions.

(i) *Detailed testing of finished gasoline batches.* An auditor 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.

(2) Obtain the volume documentation and laboratory analysis for each selected finished gasoline batch.

(3) Compare the reported volume for each selected finished gasoline batch to the volume documentation and report any exceptions.

(4) Compare the reported properties for each selected finished gasoline batch to the laboratory analysis and report any exceptions.

(5) Compare the reported test methods used for each selected finished gasoline batch to the laboratory analysis and report any exceptions.

(6) For a blending manufacturer, confirm that the laboratory analysis includes test results for oxygenate content, if applicable, and distillation parameters (*i.e.,* T10, T50, T90, final boiling point, and percent residue). For a blending manufacturer not required to measure oxygenate content, confirm that records demonstrate that the PCG or blendstock contained no oxygenate, no oxygenate was added to the final gasoline batch, and the blending manufacturer did not account for oxygenate added downstream under § 1090.710.

(j) *Detailed testing of blendstock batches.* In the case of adding blendstock to TGP or PCG under § 1090.1320(a)(2), an auditor must review a detailed listing of blendstock batches as follows:

(1) Select a representative sample of blendstock batches from the batch reports submitted under subpart J of this part.

(2) Obtain the volume documentation and the laboratory analysis for each selected blendstock batch.

(3) Compare the reported volume for each selected blendstock batch to the volume documentation and report any exceptions.

(4) Compare the reported properties for each selected blendstock batch to the laboratory analysis and report any exceptions.

(5) Compare the reported test methods used for each selected blendstock batch to the laboratory analysis and report any exceptions.

(6) For blending a manufacturer not required to measure oxygenate content, confirm that records demonstrate that the PCG or blendstock contained no oxygenate, no oxygenate was added to the final gasoline batch, and the blending manufacturer did not account for oxygenate added downstream under § 1090.710.

§ 1090.1815 General procedures for gasoline importers.

An auditor must perform the procedures in this section for a gasoline importer.

(a) *Registration and EPA reports.* An auditor must review registration and EPA reports for a gasoline importer as specified in § 1090.1810(a).

(b) *Listing of imports.* An auditor 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 and report any variances.

(6) Report in the attestation report the total imported volume for each product type.

(c) *Listing of batches.* An auditor 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 obtained under paragraph (b)(1) of this section for each product type and report 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.* An auditor 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.* An auditor 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 and report 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 L of this part and report any exceptions.

(f) *Detailed testing of BOB batches.* An auditor 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 and report any exceptions.

(3) Compare the reported properties for each selected BOB batch to the laboratory analysis and report any exceptions.

(4) Compare the reported test methods used for each selected BOB batch to the laboratory analysis and report 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 and report any exceptions.

(7) Confirm that the importer participates in the NFSP under § 1090.1405, if applicable.

(g) *Detailed testing of finished gasoline imports.* An auditor 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 and report 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 L of this part and report any exceptions.

(h) *Detailed testing of finished gasoline batches.* An auditor 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 and report any exceptions.

(3) Compare the reported properties for each selected finished gasoline batch to the laboratory analysis and report any exceptions.

(4) Compare the reported test methods used for each selected finished gasoline batch to the laboratory analysis and report any exceptions.

(i) *Additional procedures for certain gasoline imported by rail or truck.* An auditor must perform the following additional procedures for an importer that imports 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)(1) 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(a)(2).

(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 N 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 N 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, an auditor must perform the procedures in this section for a gasoline manufacturer that imports GTAB under § 1090.1615.

(a) *Listing of GTAB imports.* An auditor 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 and report 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.* An auditor 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 listing of GTAB imports in paragraph (a)(6) of this section and report any variances.

(c) *Detailed testing of GTAB imports.* An auditor must review a detailed listing of GTAB imports as follows:

(1) Select a representative sample from the listing of GTAB imports obtained under 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 and report any exceptions.

(d) *Detailed testing of GTAB batches.* An auditor must review a detailed listing of GTAB batches as follows:

(1) Select a representative sample from the GTAB 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 and report any exceptions.

(e) *GTAB tracing.* An auditor must trace and review the movement of GTAB from importation to gasoline production 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 each selected

GTAB batch from importation to gasoline production.

(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) Match the location of the facility where gasoline was produced from each selected GTAB batch to the location where each selected 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 and report any discrepancies.

§ 1090.1825 Additional procedures for PCG used to produce gasoline.

In addition to any applicable procedures required under § 1090.1810, an auditor must perform the procedures in this section for a gasoline manufacturer that produces gasoline from PCG under § 1090.1320.

(a) *Listing of PCG batches.* An auditor 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) and report any variances.

(b) *Detailed testing of PCG batches.* An auditor must review a detailed listing of PCG batches as follows:

(1) Select a representative sample from the PCG batch reports obtained under paragraph (a)(1) 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 and report any exceptions.

(4) For each selected PCG batch, 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 and report any exceptions.

(6) Compare the product type and grade for each selected PCG batch to the associated PTDs and report any exceptions.

(7) Compare the reported properties for each selected PCG batch to the laboratory analysis and report any exceptions.

(8) Compare the reported test methods used for each selected PCG batch to the laboratory analysis and report any exceptions.

§ 1090.1830 Alternative procedures for certified butane blenders.

An auditor must use the procedures in this section instead of or in addition to the applicable procedures in § 1090.1810 for a certified butane blender that blends certified butane into PCG under § 1090.1320(b).

(a) *Registration and EPA reports.* An auditor 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 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 and report 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 and report 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.* An auditor must perform an inventory reconciliation analysis review as follows:

(1) Obtain an inventory reconciliation analysis from the certified butane blender for each butane 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 and report any variances.

(4) Compare the total volume of certified butane received from the batch reports obtained under paragraph (a)(1) of this section to the inventory reconciliation analysis and report any variances.

(5) Compare the total volume of certified butane blended from the batch reports to the inventory reconciliation analysis and report any variances.

(6) Report in the attestation report the total volume of certified butane received and blended.

(c) *Listing of certified butane receipts.* An auditor must review a listing of certified butane receipts as follows:

(1) Obtain a detailed listing of all certified butane batches received at the butane 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 and report any variances.

(d) *Detailed testing of certified butane batches.* An auditor 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 and report any exceptions.

(4) Compare the reported properties for each selected certified butane batch to the laboratory analysis and report any exceptions.

(5) Compare the reported test methods used for each selected certified butane batch to the laboratory analysis and report any exceptions.

(6) Confirm that the butane meets the standards for certified butane under subpart C of this part and report any exceptions.

(e) *Quality control review.* An auditor 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(b)(4) and report any discrepancies.

§ 1090.1835 Alternative procedures for certified pentane blenders.

(a) An auditor must use the procedures in this section instead of or in addition to the applicable procedures in § 1090.1810 for a certified pentane blender that blends certified pentane into PCG under § 1090.1320(b).

(b) An auditor 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.

An auditor must perform the procedures in this section for a gasoline manufacturer that complies with the standards in subpart C of this part using the procedures specified in subpart H of this part.

(a) *Annual compliance demonstration review.* An auditor 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 a gasoline refiner or blending manufacturer, compare the gasoline production volume from the annual compliance report to the inventory reconciliation analysis under § 1090.1810(b) and report any variances.

(ii) For a gasoline importer, compare the gasoline import volume from the annual compliance report to the corresponding volume from the listing of imports under § 1090.1815(b) and report 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)(i).

(ii) Unadjusted average sulfur concentration, per § 1090.745(b), and 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.

(v) Net average sulfur concentration, per § 1090.745(c), and net average benzene concentration, per § 1090.745(d).

(4) Compare the recalculated values in paragraph (a)(3) of this section to the reported values in the annual compliance reports and report 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.* An auditor 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 and report 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.* An auditor 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 and report any variances.

(4) For an importer, the procedures of this paragraph (c) apply at the company level.

(d) *Company-level credit reconciliation.* An auditor 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.* An auditor must perform the following procedures for a gasoline manufacturer that recertifies a BOB under § 1090.740 and incurs a deficit:

(1) 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 and report any exceptions.

(6) Recalculate the deficits in accordance with the provisions of § 1090.740 and report any discrepancies.

(7) Confirm that the deficits are included in the annual compliance demonstration calculations and report any exceptions.

§ 1090.1845 Procedures related to meeting performance-based measurement and statistical quality control for test methods.

(a) *General provisions.* (1) An auditor must conduct the procedures specified in this section for a gasoline manufacturer.

(2) An auditor 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 employs, contracts, or subcontracts an external specialist, all the requirements in § 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. A third-party laboratory may also arrange for an auditor to perform a single attestation engagement on the third-party laboratory and make that available to gasoline manufacturers that have testing performed by the third-party laboratory.

(b) *Non-referee method qualification 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 procedures listed in § 1090.1360(d), the auditor must review the following:

(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) Confirm that the gasoline manufacturer supplied the supporting documentation for each test method specified in paragraph (b)(1) of this section and report any exceptions.

(4) If an auditor has previously reviewed supporting documentation under this paragraph (b) 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) Confirm that the facility completed the qualification procedures and report any exceptions.

(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 a listing from the laboratory of the instruments and period when the instruments were used to measure gasoline parameters during the compliance period for batches selected as part of the representative sample under § 1090.1810.

(2) Obtain statistical quality assurance data and control charts demonstrating ongoing quality testing to meet the accuracy and precision requirements specified in § 1090.1375 or 40 CFR 80.47, as applicable.

(3) Confirm that the facility performed statistical quality assurance monitoring of its instruments under § 1090.1375 and report any exceptions.

(4) Report as a finding in the attestation report the instrument lists obtained under paragraph (d)(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, an auditor must perform the procedures specified in this section for a gasoline manufacturer that relies on an in-line blending waiver under § 1090.1315.

(a) Obtain a copy of the gasoline manufacturer's in-line blending waiver submission and EPA's approval letter.

(b) Confirm that the sampling procedures and composite calculations conform to specifications as specified in § 1090.1315(a)(2).

(c) Review the gasoline manufacturer'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.

(d) Confirm that the gasoline manufacturer corrected their operations because of previous audits, if applicable.

(e) Confirm that the equipment and procedures are not materially changed from the gasoline manufacturer's in-line blending waiver. In cases of material change in equipment or procedure, confirm that the gasoline manufacturer updated their in-line blending waiver and report any exceptions.

(f) Perform any additional procedures unique to the blending operation, as specified in the in-line blending waiver, and report any findings, variances, or exceptions, as applicable.

(g) Confirm that the gasoline manufacturer has complied with all provisions related to their in-line blending waiver and report any exceptions.

[FR Doc. 2020–23164 Filed 12–3–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL REGISTER

Vol. 85 Friday,

No. 234 December 4, 2020

Part III

Securities and Exchange Commission

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Adopt FINRA Rule 4111 (Restricted Firm Obligations) and FINRA Rule 9561 (Procedures for Regulating Activities Under Rule 4111); Notice

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90527; File No. SR–FINRA–2020–041]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Adopt FINRA Rule 4111 (Restricted Firm Obligations) and FINRA Rule 9561 (Procedures for Regulating Activities Under Rule 4111)

November 27, 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 November 16, 2020, the 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. 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 (1) adopt FINRA Rule 4111 (Restricted Firm Obligations) to require member firms that are identified as ''Restricted Firms'' to maintain a deposit in a segregated account from which withdrawals would be restricted, adhere to specified conditions or restrictions, or comply with a combination of such obligations; and (2) adopt a new FINRA Rule 9561 (Procedures for Regulating Activities Under Rule 4111), and amend FINRA Rule 9559 (Hearing Procedures for Expedited Proceedings Under the Rule 9550 Series), to create a new expedited proceeding to implement proposed Rule 4111.[3] In addition, FINRA proposes to adopt Capital Acquisition Broker (''CAB'') Rule 412 (Restricted Firm Obligations), to clarify that member firms that have elected to be treated as CABs would be subject to proposed FINRA Rule 4111, and to amend Funding Portal Rule 900(a) (Application of FINRA Rule 9000 Series (Code of Procedure) to Funding Portals), to clarify that funding portals would not be subject to proposed FINRA Rule 9561.

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

Background

FINRA has been engaged in an ongoing effort to enhance its programs to address the risks that can be posed to investors and the broader market by individual brokers and member firms that have a history of misconduct. As part of these efforts, FINRA is proposing to adopt Rule 4111, which would impose obligations on member firms that have significantly higher levels of risk-related disclosures than similarly sized peers. FINRA would preliminarily identify these member firms by using numeric, threshold-based criteria and several additional steps that would guard against misidentification. The obligations could include requiring a member firm to maintain a specific deposit amount, with cash or qualified securities, in a segregated account at a bank or clearing firm, from which the member firm could make withdrawals only with FINRA's approval. The obligations also could include conditions or restrictions on the operations and activities of the member firm and its associated persons that relate to, and are designed to address the concerns indicated by, the preliminary identification criteria and protect investors and the public interest. FINRA also is proposing to adopt FINRA Rule 9561, and amend FINRA Rule 9559, to create a new expedited proceeding to implement proposed Rule 4111.

FINRA has a number of tools to deter and remedy misconduct by member firms and the individuals they hire, including review of membership applications, focused examinations, risk monitoring and disciplinary actions. These tools have been effective in identifying and addressing a range of misconduct by individuals and member firms, and FINRA has continued to strengthen them. In recent years, for example, FINRA has enhanced its key investor protection rules and examination programs, expanded its risk-based monitoring of brokers and member firms, and deployed new technologies designed to make its regulatory efforts more effective and efficient.[4]

These efforts have strengthened protections for investors and the markets, but persistent compliance issues continue to arise in some FINRA member firms, which are a top focus of FINRA regulatory programs. While historically small in number, such firms generally do not carry out their supervisory obligations to ensure compliance with applicable securities laws and regulations and FINRA rules, and they act in ways that could harm their customers and erode trust in the brokerage industry. Recent academic studies, for example, find that some firms persistently employ brokers who engage in misconduct, and that misconduct can be concentrated at these firms. These studies also provide evidence that the past disciplinary and other regulatory events associated with a firm or individual can be predictive of similar future events.[5] While these firms may eventually be forced out of the industry through FINRA action or otherwise, these patterns indicate a persistent, if limited, population of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] This reflects a different numbering than was originally proposed. *See Regulatory Notice* 19–17 (proposing to number the proposed new expedited proceeding rule as Rule ''9559'' and to renumber current Rule 9559 as Rule ''9560'').

[4] For example, in October 2018, FINRA announced plans to consolidate its Examination and Risk Monitoring Programs, integrating three separate programs into a single, unified program to drive more effective oversight and greater consistency, eliminate duplication and create a single point of accountability for the examination of member firms. The consolidation brings those programs under a single framework designed to better direct and align examination resources to the risk profile and complexity of member firms. FINRA is conducting its examinations under this unified program in 2020.

[5] For example, in 2015 FINRA's Office of the Chief Economist (''OCE'') published a study that examined the predictability of disciplinary and other disclosure events associated with investor harm based on past similar events. The OCE study showed that past disclosure events, including regulatory actions, customer arbitrations and litigations of brokers, have significant power to predict future investor harm. *See* Hammad Qureshi & Jonathan Sokobin, Do Investors Have Valuable Information About Brokers? (OCE Working Paper, Aug. 2015). A subsequent academic research paper presented evidence that suggests a higher rate of new disciplinary and other disclosure events is highly correlated with past disciplinary and other disclosure events, as far back as nine years prior. *See* Mark Egan, Gregor Matvos, & Amit Seru, The Market for Financial Adviser Misconduct, J. Pol. Econ. 127, no. 1 (Feb. 2019): 233–295.

firms with a history of misconduct that may not be acting appropriately as a first line of defense to prevent customer harm by their brokers.

Such firms expose investors to real risk. For example, FINRA has identified certain firms that have a concentration of associated persons with a history of misconduct, and some of these firms consistently hire such individuals and fail to reasonably supervise their activities. These firms generally have a retail business engaging in cold calling to make recommendations of securities, often to vulnerable customers. FINRA has also identified groups of individual brokers who move from one firm of concern to another firm of concern. Such firms and their associated persons often have substantial numbers of disclosures on their records. In such situations, FINRA closely examines the firms' and brokers' conduct, and where appropriate, FINRA will bring enforcement actions to bar or suspend the firms and individuals involved.

However, individuals and firms with a history of misconduct can pose a particular challenge for FINRA's existing examination and enforcement programs. In particular, examinations can identify compliance failures—or imminent failures—and prescribe remedies to be taken, but examiners are not empowered to require a firm to change or limit its business operations in a particular manner without an enforcement action. While these constraints on the examination process protect firms from potentially arbitrary or overly onerous examination findings, an individual or firm with a history of misconduct can take advantage of these limits to simply continue activities that pose risk of harm to investors until they result in an enforcement action.

Enforcement actions in turn can only be brought after a rule has been violated and any resulting customer harm has already occurred. In addition, these proceedings can take significant time to develop, prosecute and conclude, during which time the individual or firm is able to continue misconduct, with significant risks of additional harm to customers and investors. Parties with serious compliance issues often will litigate enforcement actions brought by FINRA, which potentially involves a hearing and multiple rounds of appeals, forestalling the imposition of disciplinary sanctions for an extended period. For example, an enforcement proceeding could involve a hearing before a Hearing Panel, numerous motions, an appeal to the National Adjudicatory Council (''NAC''), and a further appeal to the SEC. Moreover, even when a FINRA Hearing Panel imposes a significant sanction, the sanction is stayed during appeal to the NAC, many sanctions are automatically stayed on appeal to the SEC, and they potentially can be stayed during appeal to the courts. And when all appeals are exhausted, the firm may have withdrawn its FINRA membership and shifted its business to another member or other type of financial firm, limiting FINRA's jurisdiction and avoiding the sanction, including making restitution to customers.

Temporary cease and desist proceedings, while useful, do not always provide an effective remedy for potential ongoing harm to investors during the enforcement process.[6] Temporary cease and desist proceedings are available only in narrowly defined circumstances. Moreover, initiation by FINRA of a temporary cease and desist action does not necessarily enable more rapid intervention, because FINRA must be prepared to file the underlying disciplinary complaint at the same time.

In addition, by the time sanctions are imposed, as noted above, the firm may have exited the industry, thereby limiting FINRA's jurisdiction over the misconduct. In such circumstance, the firm may also fail to pay arbitration awards owed to claimants, leaving investors uncompensated and diminishing confidence in the securities markets.

Therefore, FINRA is strengthening its tools to respond to firms and brokers with a significant history of misconduct, and the firms that employ those brokers, several of which are described below.

Additional Steps Undertaken by FINRA

To address these problems, FINRA has undertaken the following:

➢ Published *Regulatory Notice* 18–15, which rearticulates the obligation of member firms to implement heightened supervisory procedures tailored to the associated persons with a history of misconduct;

➢ Proposed rule amendments that would require a member firm to conduct with FINRA a materiality consultation before allowing persons with a history of misconduct to become owners, control persons, principals or registered persons of a member firm; authorize the imposition in a disciplinary proceeding of conditions and restrictions on the activities of a respondent member firm or respondent broker that are reasonably necessary for the purpose of preventing customer harm, and require a respondent broker's member firm to adopt heightened supervisory procedures for such broker, when a disciplinary matter is appealed to the NAC or called for NAC review; require firms that apply to continue associating with a statutorily disqualified person to include in that application an interim plan of heightened supervision that would be effective throughout the application process; and allow the disclosure through FINRA BrokerCheck of the status of a member firm as a ''taping firm'' under FINRA Rule 3170 (Tape Recording of Registered Persons by Certain Firms);[7]

➢ Published *Regulatory Notice* 18–17, which announced revisions to the FINRA Sanction Guidelines;

➢ Raised fees for statutory disqualification applications;[8] and

➢ Revised the qualification examination waiver guidelines to permit FINRA to more broadly consider past misconduct when considering examination waiver requests.[9]

While these efforts should help mitigate the risks posed by individual brokers with a history of misconduct, challenges remain where a member firm itself has a concentration of such brokers—in some cases because the firm seeks out such brokers—or otherwise has a history of substantial compliance failures.

Proposed Rule 4111 (Restricted Firm Obligations)

FINRA is proposing to adopt Rule 4111 (Restricted Firm Obligations), a new rule that would use numeric thresholds based on firm-level and individual-level disclosure events and impose a Restricted Deposit Requirement on member firms that present a high degree of risk to the investing public. FINRA believes that the direct financial impact of a restricted deposit is most likely to change such member firms' behavior—and therefore protect investors. An added benefit of this proposal would be to preserve member firm funds for payment of arbitration awards against them and their associated persons. The proposal would consider ''Covered Pending Arbitration Claims'' [10] and

[6] *See* FINRA Rule 9800 Series (Temporary and Permanent Cease and Desist Orders).

[7] *See* Securities Exchange Act Release No. 88600 (April 8, 2020), 85 FR 20745 (April 14, 2020) (Notice of Filing of File No. SR–FINRA–2020–011); *see also Regulatory Notice* 18–16 (April 2018).

[8] *See* Securities Exchange Act Release No. 83181 (May 7, 2018), 83 FR 22107 (May 11, 2018) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2018–018).

[9] *See Regulatory Notice* 18–16 (April 2018).

[10] The term ''Covered Pending Arbitration Claim'' is defined in proposed Rule 4111(i)(2) to mean, for purposes of Rule 4111, an investment-related, consumer initiated claim filed against the member or its associated persons in any arbitration forum

Continued

unpaid arbitration awards [11] in determining the size of a Restricted Firm's ''Restricted Deposit Requirement.'' [12] The proposal also would establish presumptions that, when assessing an application by a member firm or former member firm that was previously designated as a Restricted Firm for withdrawal from a Restricted Deposit Account,[13] the Department of Member Regulation (''Department'') shall: (i) Deny an application for withdrawal if the member firm, the member firm's Associated Persons who are owners or control persons, or the former member firm have any Covered Pending Arbitration Claims or unpaid arbitration awards, or if the member firm's Associated Persons have any Covered Pending Arbitration Claims or unpaid arbitration awards relating to arbitrations outstanding that involved conduct or alleged conduct that occurred while associated with the member firm; but (ii) approve a former member firm's application for withdrawal when that former member firm commits in the manner specified by the Department to use the amount it seeks to withdraw from its Restricted Deposit to pay the former member firm's specified unpaid arbitration awards.

The proposed rule would create a multi-step process for FINRA's determination of whether a member firm raises investor-protection concerns substantial enough to require that it be subject to additional obligations. Those obligations could include a requirement to maintain a deposit of cash or qualified securities in an account from which withdrawals would be restricted, or conditions or restrictions on the member firm's operations that are necessary or appropriate for the protection of investors and in the public interest. The proposed rule would give each affected member firm several ways to affect outcomes, including a one-time opportunity to reduce staffing so as to no longer trigger the preliminary identification criteria and numeric thresholds. The firm also could explain to the Department why it should not be subject to a Restricted Deposit Requirement or propose alternatives, and the firm could challenge a Department determination by requesting a hearing before a Hearing Officer in an expedited proceeding.

The proposed multi-step process includes numerous features designed to narrowly focus the new obligations on the firms most of concern. As the flow chart in Exhibit 2d reflects, this process is akin to a ''funnel.'' The top of the funnel applies to the range of member firms with the most disclosures, with a narrowing in the middle of the potential member firms that may be subject to additional obligations, and the bottom of the funnel reflecting the smaller number of member firms that are determined to present high risks to the investing public.

➢ General (Proposed Rule 4111(a))

Proposed Rule 4111(a) would require a member designated as a Restricted Firm to establish a Restricted Deposit Account and maintain in that account deposits of cash or qualified securities with an aggregate value that is not less than the member's Restricted Deposit Requirement, except in certain identified situations, and be subject to conditions or restrictions on the member's operations as determined by the Department to be necessary or appropriate for the protection of investors and in the public interest.

➢ Annual Calculation by FINRA of the Preliminary Criteria for Identification (Proposed Rule 4111(b))

The multi-step process would begin with an annual calculation. As explained more below, proposed Rule 4111(b) would require the Department to calculate annually (on a calendar-year basis) the ''Preliminary Identification Metrics'' [14] to determine whether a member firm meets the ''Preliminary Criteria for Identification.'' [15] A key driver of that is whether a member firm's ''Preliminary Identification Metrics'' meet quantitative, risk-based ''Preliminary Identification Metrics Thresholds.'' [16]

Several principles guided FINRA's development of the proposed Preliminary Criteria for Identification and the proposed Preliminary Identification Metrics Thresholds. The criteria and thresholds are intended to be replicable and transparent to FINRA and affected member firms; employ the most complete and accurate data available to FINRA; be objective; account for different firm sizes and business profiles; and target the sales-practice concerns that are motivating the proposal. These criteria are intended to identify member firms that present a high risk but avoid imposing obligations on member firms whose risk profile and activities do not warrant such obligations.

Using these guiding principles, FINRA is proposing numeric thresholds based on six categories of events or conditions, nearly all of which are based on information disclosed through the Uniform Registration Forms.[17] The six categories, collectively defined as the ''Disclosure Event and Expelled Firm Association Categories,'' [18] are:

1. Registered Person Adjudicated Events; [19]

2. Registered Person Pending Events; [20]

that is unresolved; and whose claim amount (individually or, if there is more than one claim, in the aggregate) exceeds the member's excess net capital. The claim amount includes claimed compensatory loss amounts only, not requests for pain and suffering, punitive damages or attorney's fees, and shall be the maximum amount for which the member or associated person, as applicable, is potentially liable regardless of whether the claim was brought against additional persons or the associated person reasonably expects to be indemnified, share liability or otherwise lawfully avoid being held responsible for all or part of such maximum amount. This term conforms, in relevant part, to the definition of Covered Pending Arbitration Claim in Rule 1011(c). *See* Securities Exchange Act Release No. 88482 (March 26, 2020), 85 FR 18299 (April 1, 2020) (Order Approving File No. SR–FINRA–2019–030).

[11] For purposes of this Form 19b–4, ''unpaid arbitration awards'' also includes unpaid settlements related to arbitrations.

[12] The term ''Restricted Deposit Requirement'' is defined in proposed Rule 4111(i)(15).

[13] *See* proposed Rule 4111(i)(14) (proposed definition of ''Restricted Deposit Account'').

[14] *See* proposed Rule 4111(i)(10) (definition of ''Preliminary Identification Metrics'').

[15] *See* proposed Rule 4111(i)(9) (definition of ''Preliminary Criteria for Identification'').

[16] *See* proposed Rule 4111(i)(11) (definition of ''Preliminary Identification Metrics Thresholds'').

[17] One of the event categories, Member Firm Adjudicated Events, includes events that are derived from customer arbitrations filed with FINRA's dispute resolution forum.

[18] *See* proposed Rule 4111(i)(4).

[19] ''Registered Person Adjudicated Events,'' defined in proposed Rule 4111(i)(4)(A), means any one of the following events that are reportable on the registered person's Uniform Registration Forms: (i) A final investment-related, consumer-initiated customer arbitration award or civil judgment against the registered person in which the registered person was a named party, or was a ''subject of'' the customer arbitration award or civil judgment; (ii) a final investment-related, consumer-initiated customer arbitration settlement, civil litigation settlement or a settlement prior to a customer arbitration or civil litigation for a dollar amount at or above $15,000 in which the registered person was a named party or was a ''subject of'' the customer arbitration settlement, civil litigation settlement or a settlement prior to a customer arbitration or civil litigation; (iii) a final investment-related civil judicial matter that resulted in a finding, sanction or order; (iv) a final regulatory action that resulted in a finding, sanction or order, and was brought by the SEC or Commodity Futures Trading Commission (''CFTC''), other federal regulatory agency, a state regulatory agency, a foreign financial regulatory authority, or a self-regulatory organization; or (v) a criminal matter in which the registered person was convicted of or pled guilty or nolo contendere (no contest) in a domestic, foreign, or military court to any felony or any reportable misdemeanor.

[20] ''Registered Person Pending Events,'' defined in proposed Rule 4111(i)(4)(B), means any one of the following events associated with the registered person that are reportable on the registered person's

3. Registered Person Termination and Internal Review Events; [21]

4. Member Firm Adjudicated Events; [22]

5. Member Firm Pending Events; [23] and

6. Registered Persons Associated with Previously Expelled Firms (also referred to as the Expelled Firm Association category).[24]

To calculate whether a member firm meets the Preliminary Criteria for Identification, the Department would first compute the Preliminary Identification Metrics for each of the Disclosure Event and Expelled Firm Association Categories. Each category's Preliminary Identification Metric computation would start with a calculation of the sum of the pertinent disclosure events or, for the Expelled Firm Association category, the sum of the Registered Persons Associated with Previously Expelled Firms. For the adjudicated disclosure-event based categories, the counts would include disclosure events that were resolved during the prior five years from the date of the calculation. For the pending events categories and pending internal reviews, the counts would include disclosure events that are pending as of the date of the calculation. In addition, for the three Registered Person disclosure-event based categories, the counts would include disclosure events across all Registered Persons In-Scope, which is defined to include persons registered with the member firm for one or more days within the one year prior to the calculation date.[25]

Each of those six sums would then be standardized to determine the member's six Preliminary Identification Metrics. For the five ''Registered Person and Member Firm Events'' categories (Categories 1–5 above),[26] the proposed Preliminary Identification Metrics are in the form of an average number of events per registered broker, calculated by taking each category's sum and dividing it by the number of Registered Persons In-Scope. The sixth Preliminary Identification Metric—the proposed Expelled Firm Association Metric—is in the form of a percentage concentration at the member firm of Registered Persons Associated with Previously Expelled Firms. This concentration is calculated by taking the number of Registered Persons Associated with Previously Expelled Firms and dividing it by the number of Registered Persons In-Scope.

A firm's six Preliminary Identification Metrics are used to determine if the member firm meets the Preliminary Criteria for Identification. To meet the Preliminary Criteria for Identification, a member firm would need to meet the Preliminary Identification Metrics Thresholds, set forth in proposed Rule 4111(i)(11), for two or more of the appropriate metrics listed above for its size and, if it does, one of these metrics must be for adjudicated events or the Expelled Firm Association Metric, and the firm must have two or more Registered Person and Member Firm Events (*i.e.,* events in categories besides the Registered Persons Associated with Previously Expelled Firms category).[27] This involves analyzing the extent to which the Preliminary Identification Metrics meet the specified numeric Preliminary Identification Metrics Thresholds and meet additional conditions intended to prevent a member firm from becoming potentially subject to additional obligations solely as a result of pending matters or a single event or condition.[28] Specifically, the Department would:

- First, pursuant to proposed Rules 4111(b) and (i)(9)(A), evaluate whether two or more of the member firm's Preliminary Identification Metrics are equal to or more than the corresponding Preliminary Identification Metrics Thresholds for the member firm's size, and whether at least one of those Preliminary Identification Metrics is the Registered Person Adjudicated Event Metric, the Member Firm Adjudicated Event Metric, or the Expelled Firm Association Metric; and
- second, pursuant to proposed Rules 4111(b) and (i)(9)(B), evaluate whether the member firm has two or more Registered Person or Member Firm Events (*i.e.,* two or more events from Categories 1–5 above).

If all of these conditions are met, the member firm would meet the Preliminary Criteria for Identification.

Each specific numeric threshold in the Preliminary Identification Metrics Thresholds grid in proposed Rule 4111(i)(11) is a number which represents outliers with respect to peers for the type of events in the category (*i.e.,* the firm is at the far tail of the respective category's distribution), which is intended to preliminarily

Uniform Registration Forms: (i) A pending investment-related civil judicial matter; (ii) a pending investigation by a regulatory authority; (iii) a pending regulatory action that was brought by the SEC or CFTC, other federal regulatory agency, a state regulatory agency, a foreign financial regulatory authority, or a self-regulatory organization; or (iv) a pending criminal charge associated with any felony or any reportable misdemeanor. Registered Person Pending Events does not include pending arbitrations, pending civil litigations, or consumer-initiated complaints that are reportable on the registered person's Uniform Registration Forms.

[21] ''Registered Person Termination and Internal Review Events,'' defined in proposed Rule 4111(i)(4)(C), means any one of the following events associated with the registered person at a previous member firm that are reportable on the registered person's Uniform Registration Forms: (i) A termination in which the registered person voluntarily resigned, was discharged or was permitted to resign from a previous member after allegations; or (ii) a pending or closed internal review by a previous member. FINRA has revised this definition, from the version proposed in *Regulatory Notice* 19–17 (May 2019), to clarify that termination and internal review disclosures concerning a person whom a member firm terminated would not impact that member firm's own Registered Person Termination and Internal Review Metric; rather, they would only impact the metrics of member firms that subsequently register the terminated individual.

[22] ''Member Firm Adjudicated Events,'' defined in proposed Rule 4111(i)(4)(D), means any one of the following events that are reportable on the member firm's Uniform Registration Forms or based on customer arbitrations filed with FINRA's dispute resolution forum: (i) A final investment-related, consumer-initiated customer arbitration award in which the member was a named party; (ii) a final investment-related civil judicial matter that resulted in a finding, sanction or order; (iii) a final regulatory action that resulted in a finding, sanction or order, and was brought by the SEC or CFTC, other federal regulatory agency, a state regulatory agency, a foreign financial regulatory authority, or a self-regulatory organization; or (iv) a criminal matter in which the member was convicted of or pled guilty or nolo contendere (no contest) in a domestic, foreign, or military court to any felony or any reportable misdemeanor.

[23] ''Member Firm Pending Events,'' defined in proposed Rule 4111(i)(4)(E), means any one of the same kinds of events as the ''Registered Person Pending Events,'' but that are reportable on the member firm's Uniform Registration Forms.

[24] ''Registered Persons Associated with Previously Expelled Firms,'' defined in proposed Rule 4111(i)(4)(F), means any ''Registered Person In-Scope'' who was registered for at least one year with a previously expelled firm and whose registration with the previously expelled firm terminated during the ''Evaluation Period'' (*i.e.,* the prior five years from the ''Evaluation Date,'' which is the annual date as of which the Department calculates the Preliminary Identification Metrics). *See* proposed Rule 4111(i)(5), (6), and (13) (proposed definitions of ''Evaluation Date,'' ''Evaluation Period,'' and ''Registered Persons In-Scope''). This proposed definition is narrower than the definition proposed in *Regulatory Notice* 19–17.

[25] *See* proposed Rule 4111(i)(13).

[26] *See* proposed Rule 4111(i)(12) (definition of Registered Person and Member Firm Events).

[27] Including an Expelled Firm Association Metric in the Preliminary Criteria for Identification is similar to how FINRA Rule 3170 (Tape Recording of Registered Persons by Certain Firms) imposes recording requirements on firms with specific percentages of registered persons who were previously associated with disciplined firms.

[28] The purpose of ensuring that a firm does not meet the Preliminary Criteria for Identification solely because of pending matters is because FINRA recognizes that pending matters include disclosure events that may remain unresolved or that may subsequently be dismissed or concluded with no adverse action. As explained in more detail in the Economic Impact Assessment, FINRA also evaluated the impact of including and excluding pending matters from the Preliminary Criteria for Identification. Based on this evaluation, FINRA has included pending matters in the proposed criteria because they are critical to identifying firms that pose greater risks to their customers.

identify member firms that present significantly higher risk than a large percentage of the membership. In addition, there are numeric thresholds for seven different firm sizes, to ensure that each member firm is compared only to its similarly sized peers.[29] As explained more below in the Economic Impact Assessment, based on recent history FINRA expects that its annual calculations will identify between 45–80 member firms that meet the Preliminary Criteria for Identification.[30]

The following three examples demonstrate—in practical terms—the point at which a member firm's Preliminary Identification Metrics would meet the Preliminary Identification Metrics Thresholds in proposed Rule 4111(i)(11):

	Preliminary identification metrics thresholds	Practical equivalent
Example 1 (member firm size between 1–4 registered persons).	The Preliminary Identification Metrics Threshold for the Registered Person Adjudicated Event Metric, for a member firm that has between one and four Registered Persons In-Scope as of the Evaluation Date,[31] is 0.50 (or 0.50 events per Registered Broker In-Scope).	For a member firm with four Registered Persons In-Scope as of the Evaluation Date, the member would meet the Preliminary Identification Metrics Threshold for the Registered Person Adjudicated Event Metric if the sum of its four Registered Persons In-Scope's Adjudicated Events, which reached a resolution over the five years before the Evaluation Date, was *two or more.* (4 Registered Persons In-Scope) * (0.50 Preliminary Identification Metrics Threshold for the Registered Person Adjudicated Event Metric) = (2 Adjudicated Events)
Example 2 (member firm size between 20–50 registered persons).	The Preliminary Identification Metrics Threshold for the Member Firm Adjudicated Event Metric, for a member firm that has between 20–50 Registered Persons In-Scope as of the Evaluation Date, is 0.20 (or 0.20 events per Registered Broker In-Scope).	For a member firm with 50 Registered Persons In-Scope as of the Evaluation Date, the member firm would meet the Preliminary Identification Metrics Threshold for the Member Firm Adjudicated Event Metric if the sum of the member firm's Adjudicated Events, which reached a resolution over the five years before the Evaluation Date, was *ten or more.* (50 Registered Persons In-Scope) * (0.20 Preliminary Identification Metrics Threshold for the Member Firm Adjudicated Event Metric) = (10 Adjudicated Events)
Example 3 (member firm size between 51–150 registered persons).	The Preliminary Identification Metrics Threshold for the Expelled Firm Association Metric, for a member firm that has between 51–150 Registered Persons In-Scope as of the Evaluation Date, is 0.03 (or a 3% concentration level).	For a member firm with 100 Registered Persons In-Scope as of the Evaluation Date, the member firm would meet the Preliminary Identification Metrics Threshold for the Expelled Firm Association Metric if the sum of its Registered Persons Associated with Previously Expelled Firms was *three or more.* (100 Registered Persons In-Scope) * (0.03 Preliminary Identification Metrics Threshold for the Expelled Firm Association Metric) = (Three Registered Persons Associated with Previously Expelled Firms)

In a comment to *Regulatory Notice* 19–17, SIFMA requested more clarity around when the annual Evaluation Date would be. FINRA would announce the first Evaluation Date no less than 120 calendar days before the first Evaluation Date. Subsequent Evaluation Dates would be on the same month and day each year, except when that date falls on a Saturday, Sunday or federal holiday, in which case the Evaluation Date would be on the next business day.

FINRA has conducted a thorough analysis of the proposed criteria and thresholds to ensure that the proposed Preliminary Criteria for Identification preliminarily identify the types of member firms that are motivating this rule proposal.[32] As explained below, however, the proposed rule involves several additional steps to guard against the risk of misidentification.

➢ Initial Department Evaluation (Proposed Rule 4111(c)(1))

For each member firm that meets the Preliminary Criteria for Identification, the Department would conduct, pursuant to proposed Rule 4111(c)(1), an initial internal evaluation to determine whether the member firm does not warrant further review under Rule 4111. In doing so, the Department would review whether it has information to conclude that the computation of the member firm's Preliminary Identification Metrics included disclosure events or other conditions that should not have been included because they are not consistent with the purpose of the Preliminary Criteria for Identification and are not reflective of a firm posing a high degree of risk. For example, the Department may have information that the computation included disclosure events that were not sales-practice related, were duplicative (involving the same customer and the same matter), or mostly involved compliance concerns best addressed by a different regulatory response by FINRA. The Department would evaluate the events to determine, among other things, whether they

[29] Because FINRA has narrowed the definition of Registered Persons Associated with Previously Expelled Firms from the version that was originally proposed in *Regulatory Notice* 19–17, FINRA also has revised the Expelled Firm Association Metric Thresholds.

[30] Due to the revisions in the Preliminary Criteria for Identification, discussed above, and the inclusion of the year 2019 in the review period, this estimate and other corresponding estimates in the Economic Impact Assessment have changed from the ones in *Regulatory Notice* 19–17.

[31] The ''Evaluation Date'' is defined in proposed Rule 4111(i)(5) to mean the date, each calendar year, as of which the Department calculates the Preliminary Identification Metrics to determine if the member firm meets the Preliminary Criteria for Identification.

[32] OCE has tested the Preliminary Criteria for Identification, including the Preliminary Identification Metrics Thresholds, in several ways. For example, OCE has compared the firms captured by the proposed criteria to the firms that have recently been expelled or that have unpaid arbitration awards. OCE also has consulted with Department staff and examiners about whether, based on their experience, the criteria identifies firms that appear to present high risks to investors.

indicated risks to investors or market integrity, rather than, for instance, repeated violations of procedural rules.

The Department would also consider whether the member firm has addressed the concerns signaled by the disclosure events or conditions or altered its business operations, including staffing reductions, such that the threshold calculation no longer reflects the member firm's current risk profile. Essentially, the purpose of the Department's initial evaluation is to determine whether it is aware of information that would show that the member firm—despite having met the Preliminary Criteria for Identification—does not pose a high degree of risk.

Pursuant to proposed Rule 4111(c)(3), if the Department determines, after this initial evaluation, that the member firm does not warrant further review, the Department would conclude that year's Rule 4111 process for the member firm and would not seek that year to impose any obligations on it. If, however, the Department determines that the member firm does warrant further review, the Rule 4111 process would continue.

➢ One-Time Opportunity To Reduce Staffing Levels (Proposed Rule 4111(c)(2))

If the Department determines, after its initial evaluation, that a member firm warrants further review under proposed Rule 4111, such member firm—if it would be meeting the Preliminary Criteria for Identification for the first time—would have a one-time opportunity to reduce its staffing levels to no longer meet these criteria, within 30 business days after being informed by the Department. The member firm would be required to demonstrate the staff reduction to the Department by identifying the terminated individuals. The proposed rule would prohibit the member firm from rehiring any persons terminated pursuant to this option, in any capacity, for one year. A member firm that has reduced staffing levels at this stage may not use that staff-reduction opportunity again.

If the Department determines that the member firm's reduction of staffing levels results in its no longer meeting the Preliminary Criteria for Identification, the Department would close out that year's Rule 4111 process for the member firm and would not seek that year to impose any obligations on that firm. If, on the other hand, the Department determines that the member firm still meets the Preliminary Criteria for Identification even after its staff reductions, or if the member firm elects not to use its one-time opportunity to reduce staffing levels, the Department would proceed to determine the firm's maximum Restricted Deposit Requirement, and the member firm would proceed to a ''Consultation'' with the Department.

➢ FINRA's Determination of a Maximum Restricted Deposit Requirement (Proposed Rule 4111(i)(15))

For members that warrant further review after being deemed to meet the Preliminary Criteria for Identification and after the initial Department evaluation, the Department would then determine the member's maximum ''Restricted Deposit Requirement.''

The Department would tailor the member firm's maximum Restricted Deposit Requirement amount to its size, operations and financial conditions. As provided in proposed Rule 4111(i)(15), the Department would consider the nature of the member firm's operations and activities, revenues, commissions, assets, liabilities, expenses, net capital, the number of offices and registered persons, the nature of the disclosure events counted in the numeric thresholds, insurance coverage for customer arbitration awards or settlements, concerns raised during FINRA exams, and the amount of any of the firm's or its Associated Persons' ''Covered Pending Arbitration Claims'' or unpaid arbitration awards.[33] Based on a consideration of these factors, the Department would determine a maximum Restricted Deposit Requirement for the member firm that would be consistent with the objectives of the rule, but not significantly undermine the continued financial stability and operational capability of the member firm as an ongoing enterprise over the next 12 months. FINRA's intent is that the maximum Restricted Deposit Requirement should be significant enough to change the member firm's behavior but not so burdensome that it would force the member firm out of business solely by virtue of the imposed deposit requirement.

➢ Consultation (Proposed Rule 4111(d))

If the Department determines, after the process discussed above, that a member firm warrants further Rule 4111 review, the Department would consult with the member firm, pursuant to proposed Rule 4111(d). This Consultation will give the member firm an opportunity to demonstrate why it does not meet the Preliminary Criteria for Identification, why it should not be designated as a Restricted Firm, and why it should not be subject to the maximum Restricted Deposit Requirement.

In the Consultation, there would be two rebuttable presumptions: That the member firm should be designated as a Restricted Firm; and that it should be subject to the maximum Restricted Deposit Requirement. The member firm would bear the burden of overcoming those presumptions.

Proposed Rule 4111(d)(1) governs how a member may overcome these two presumptions. First, a member may overcome the presumption that it should be designated as a Restricted Firm by clearly demonstrating that the Department's calculation that the member meets the Preliminary Criteria for Identification is inaccurate because, among other things, it included events, in the six categories described above, that should not have been included because, for example, they are duplicative, involving the same customer and the same matter, or are not sales-practice related. Second, a member firm may overcome the presumption that it should be subject to the maximum Restricted Deposit Requirement by clearly demonstrating to the Department that the member firm would face significant undue financial hardship if it were required to maintain the maximum Restricted Deposit Requirement and that a lesser deposit requirement would satisfy the objectives of Rule 4111 and be consistent with the protection of investors and the public interest; or that other conditions and restrictions on the operations and activities of the member firm and its associated persons would address the

[33] The proposed factors that the Department would consider when determining a maximum Restricted Deposit Requirement have been revised from the ones proposed in Regulatory Notice 19–17. Some of the revisions are to ensure that proposed Rule 4111(i)(15) describes more accurately the factors that would be relevant to a determination of the maximum Restricted Deposit Requirement. In this regard, the ''annual revenues'' and ''net capital requirements'' factors proposed in Regulatory Notice 19–17 have been modified to ''revenues'' and ''net capital,'' and ''assets,'' ''expenses,'' and ''liabilities'' have been added as factors. Another revision clarifies that the Covered Pending Arbitration Claims and unpaid arbitration awards factors include claims and awards against the firm and its Associated Persons. The Department's consideration of claims and awards against the firm's Associated Persons would focus on claims and awards against Associated Persons who are owners or control persons and on claims and awards relating to arbitrations that involved conduct or alleged conduct that occurred while associated with the member firm. The revised proposed definition also adds the member firm's ''insurance coverage for customer arbitration awards or settlements'' as a factor. FINRA believes that, if Restricted Firms were able to procure errors and omissions policies, or other kinds of insurance coverage, for some or all of the kinds of arbitration claims that customers typically bring, that could warrant a reduced Restricted Deposit Requirement and would be behavior to encourage.

concerns indicated by the thresholds and protect investors and the public interest.

Proposed Rule 4111(d)(2) governs how the Department would schedule and provide notice of the Consultation. In a change from the proposal in *Regulatory Notice* 19–17, the Department would provide the written letter required by the rule at least seven days prior to the Consultation, and would establish a process whereby the member can request a postponement for good cause shown. These changes, which are in response to a comment on *Regulatory Notice* 19–17, are intended to ensure that the firms have sufficient time to prepare for the Consultation and to enhance the procedural protections.

Proposed Rule 4111(d)(3) provides guidance on what the Department would consider during the Consultation when evaluating whether a member firm should be designated as a Restricted Firm and subject to a Restricted Deposit Requirement. This provision also provides member firms with guidance on how to attempt to overcome the two rebuttable presumptions. For example, proposed Rule 4111(d)(3) requires that the Department consider:

- Information provided by the member firm during any meetings as part of the Consultation;
- relevant information or documents, if any, submitted by the member firm, in the manner and form prescribed by the Department, as would be necessary or appropriate for the Department to review the computation of the Preliminary Criteria for Identification;
- any plan submitted by the member firm, in the manner and form prescribed by the Department, proposing in detail the specific conditions or restrictions that the member firm seeks to have the Department consider;
- such other information or documents as the Department may reasonably request from the member firm related to the evaluation; and
- any other information the Department deems necessary or appropriate to evaluate the matter.

To the extent a member firm seeks to claim undue financial hardship, it would be the member firm's burden to support that with documents and information.

➢ Department Decision and Notice (Proposed Rule 4111(e)); No Stays

After the Consultation, proposed Rule 4111(e) would require that the Department render a Department decision. Under proposed Rule 4111(e)(1), there are three paths that decision might take:

- If the Department determines that the member firm has rebutted the presumption that it should be designated as a Restricted Firm, the Department's decision would state that the member firm will not be designated that year as a Restricted Firm.
- If the Department determines that the member firm has not rebutted the presumption that it should be designated as a Restricted Firm or the presumption that it must maintain the maximum Restricted Deposit Requirement, the Department's decision would designate the member firm as a Restricted Firm and require the member firm to promptly establish a Restricted Deposit Account, deposit and maintain in that account the maximum Restricted Deposit Requirement, and implement and maintain specified conditions or restrictions, as necessary or appropriate, on the operations and activities of the member firm and its associated persons that relate to, and are designed to address the concerns indicated by, the Preliminary Criteria for Identification and protect investors and the public interest.
- If the Department determines that the member firm has not rebutted the presumption that it should be designated as a Restricted Firm but has rebutted the presumption that it must maintain the maximum Restricted Deposit Requirement, the Department's decision would designate the member firm as a Restricted Firm; would impose no Restricted Deposit Requirement on the member firm, or would require the member firm to promptly establish a Restricted Deposit Account, deposit and maintain in that account a Restricted Deposit Requirement in such dollar amount less than the maximum Restricted Deposit Requirement as the Department deems necessary or appropriate; and would require the member firm to implement and maintain specified conditions or restrictions, as necessary or appropriate, on the operations and activities of the member firm and its associated persons that relate to, and are designed to address the concerns indicated by, the Preliminary Criteria for Identification and protect investors and the public interest.

Pursuant to proposed Rule 4111(e)(2), the Department would provide a written notice of its decision to the member firm, pursuant to proposed Rule 9561 and no later than 30 days from the latest scheduling letter provided to the member firm under proposed Rule 4111(d)(2), that states the obligations to be imposed on the member firm, if any, and the ability of the member firm to request a hearing with the Office of Hearing Officers in an expedited proceeding, as further described below.

Proposed Rule 4111(e)(2) would provide that a request for a hearing would not stay the effectiveness of the Department's decision. However, upon requesting a hearing of a Department decision that imposes a Restricted Deposit Requirement, the member firm would only be required to maintain in a Restricted Deposit Account the lesser of 25% of its Restricted Deposit Requirement or 25% of its average excess net capital during the prior calendar year, until the Office of Hearing Officers or the NAC issues its final written decision in the expedited proceeding.[34] This has one exception: A member firm that is re-designated as a Restricted Firm and is already subject to a previously imposed Restricted Deposit Requirement would be required to maintain the full amount of its Restricted Deposit Requirement until the Office of Hearing Officers or the NAC issues its final written decision in the expedited proceeding.

Considering the nature of the firms identified as Restricted Firms and the risks they present, the immediate effectiveness of the Department's decision will help protect investors during the pendency of the expedited proceeding. Moreover, FINRA believes that the no-stay provision is consistent with fairness principles, because obligations would be imposed only after firms are preliminarily identified, from among their firm-size peer group, by transparent criteria and a process that involves an initial evaluation and a consultation with the firm.

➢ Continuation or Termination of Restricted Firm Obligations (Proposed Rule 4111(f))

The proposed Restricted Firm Obligations Rule would require FINRA to determine annually whether each member firm is, or continues to be, a Restricted Firm and whether the member firm should be subject to any obligations. For this reason, proposed Rule 4111(f) contains provisions that set forth how any obligations that were imposed during the Rule 4111 process in one year are continued or terminated

[34] In *Regulatory Notice* 19–17 (May 2019), FINRA originally proposed that the member firm would be required, upon requesting a hearing, to deposit the lesser of 50% of the Restricted Deposit Requirement or 25% of the firm's average excess net capital during the prior calendar year. FINRA has revised this provision because, although the no-stay provisions are a fundamental part of how the proposed rule would protect investors, FINRA believes that this aspect of the no-stay provisions could be less burdensome than originally proposed and still achieve its intended purpose.

in that same year and in subsequent years.

Proposed Rule 4111(f)(1), titled ''Currently Designated Restricted Firms,'' establishes constraints on a member firm's ability to seek to modify or terminate, directly or indirectly, any obligations imposed pursuant to Rule 4111. Because the Restricted Firm Obligations Rule would entail annual reviews by the Department to determine whether a member firm is a Restricted Firm that should be subject to obligations, a Restricted Firm could seek each year to terminate or modify any obligations that continue to be imposed. For this reason, proposed Rule 4111 does not authorize a Restricted Firm to seek, outside of the Consultation process and any ensuing expedited proceedings after a Department decision, a separate interim termination or modification of any obligations imposed. Rather, proposed Rule 4111(f)(1) provides that a member firm that has been designated as a Restricted Firm will not be permitted to withdraw all or any portion of its Restricted Deposit Requirement, or seek to terminate or modify any deposit requirement, conditions, or restrictions that have been imposed on it, without the prior written consent of the Department. In a change from the proposal in *Regulatory Notice* 19–17, there would be a presumption that the Department shall deny an application by a member firm or former member firm that is currently designated as a Restricted Firm to withdraw all or any portion of its Restricted Deposit Requirement.[35]

Proposed Rule 4111(f)(2), titled ''Re-Designation as a Restricted Firm,'' addresses the scenario when the Department determines in one year that a member firm is a Restricted Firm, and in the following year determines that the member firm still meets the Preliminary Criteria for Identification. In that instance, the Department would re-designate the member firm as a Restricted Firm, and the obligations previously imposed on the member firm would continue unchanged, unless either the member firm or the Department requests, within seven days of the Department's decision to re-designate the member firm as a Restricted Firm, a Consultation.[36] If a Consultation is requested, the obligations previously imposed would continue unchanged unless and until the Department modifies or terminates them after the Consultation. In addition, in the Consultation process, a presumption would apply that any previously imposed Restricted Deposit Requirement, conditions or restrictions would remain effective and unchanged, absent a showing by the party seeking changes that they are no longer necessary or appropriate for the protection of investors or in the public interest. At the end of the Consultation, the Department would be required to provide written notice of its determination to the member firm, no later than 30 days from the date of the latest scheduling letter provided to the member firm under Rule 4111(d)(2).

Proposed Rule 4111(f)(3), titled ''Previously Designated Restricted Firms,'' addresses the scenario where the Department determines in one year that a member firm is a Restricted Firm, but in the following year(s) determines that the member firm or former member firm[37] either does not meet the Preliminary Criteria for Identification or should not be designated as a Restricted Firm. In that case, the member firm or former member firm would no longer be subject to any obligations previously imposed under proposed Rule 4111. There would be one exception: A former Restricted Firm would not be permitted to withdraw any portion of its Restricted Deposit Requirement without submitting an application and obtaining the Department's prior written consent for the withdrawal. Such an application would be required to include, among other things set forth in proposed Rule 4111(f)(3)(A), evidence as to whether the firm, its Associated Persons, or the former member firm have Covered Pending Arbitration Claims or any unpaid arbitration awards outstanding.

The Department would determine whether to authorize a withdrawal, in part or in whole. Proposed Rule 4111(f)(3)(B)(i) would establish a presumption that the Department shall approve an application for withdrawal if the member firm, its Associated Persons, or the former member firm have no Covered Pending Arbitration Claims or unpaid arbitration awards. Proposed Rule 4111(f)(3)(B)(ii) would establish presumptions that the Department shall: (a) Deny an application for withdrawal if the member firm, the member firm's Associated Persons who are owners or control persons, or the former member have any ''Covered Pending Arbitration Claims,'' unpaid arbitration awards, or if the member's Associated Persons have any ''Covered Pending Arbitration Claims'' or unpaid arbitration awards relating to arbitrations that involved conduct or alleged conduct that occurred while associated with the member; but (b) approve an application by a former member for withdrawal if the former member commits in the manner specified by the Department to use the amount it seeks to withdraw from its Restricted Deposit to pay the former member's specified unpaid arbitration awards.[38] The Department would be required to issue, pursuant to proposed Rule 9561, a notice of its decision on an application to withdraw from the Restricted Deposit Account within 30 days from the date the application is received by the Department.

➢ Restricted Deposit Account (Proposed Rule 4111(i)(14))

If a Department decision requires a member firm to establish a Restricted Deposit Account, proposed Rule 4111(i)(14) would govern this account. The underlying policy for the proposed account requirements is that, to make a deposit requirement effective in creating appropriate incentives to member firms that pose higher risks to change their behavior, the member firm must be restricted from withdrawing any of the required deposit amount, even if it terminates its FINRA membership.

The proposed rule would require that the Restricted Deposit Account be established, in the name of the member firm, at a bank or the member firm's clearing firm. The account must be subject to an agreement in which the bank or the clearing firm agrees: Not to permit withdrawals from the account absent FINRA's prior written consent; to keep the account separate from any other accounts maintained by the member firm with the bank or clearing firm; that the cash or qualified securities on deposit will not be used directly or indirectly as security for a loan to the member firm by the bank or the clearing firm, and will not be subject to any set-off, right, charge, security interest, lien, or claim of any kind in favor of the bank, clearing firm or any person claiming through the bank or clearing

[35] This revision, and additional revisions to proposed Rule 4111(f)(3) discussed below, are intended to make more clear the process that would guide the Department's assessment of applications for withdrawal from a Restricted Deposit Requirement.

[36] The seven-day period to request a Consultation is a revision from the proposal in *Regulatory Notice* 19–17 (May 2019), which proposed a 30-day period.

[37] *See* proposed Rule 4111(i)(7) (definition of ''Former Member'').

[38] The presumptions in proposed Rule 4111(f)(3)(B) have been modified from what was proposed in *Regulatory Notice* 19–17. In addition, in clarifying changes from *Regulatory Notice 19–17,* proposed Rule 4111(f)(3) expressly provides that the Covered Pending Arbitration Claims and unpaid arbitration awards of a member firm's ''Associated Persons'' are pertinent to an application for a withdrawal from the Restricted Deposit Requirement.

firm; that if the member firm becomes a former member, the Restricted Deposit Requirement in the account must be maintained, and withdrawals will not be permitted without FINRA's prior written consent; that FINRA is a third-party beneficiary to the agreement; and that the agreement may not be amended without FINRA's prior written consent. In addition, the account could not be subject to any right, charge, security interest, lien, or claim of any kind granted by the member.[39]

➢ Books and Records (Proposed Rule 4111(g))

Proposed Rule 4111(g) would establish new requirements to maintain books and records that evidence the member firm's compliance with the Restricted Firm Obligations Rule and any Restricted Deposit Requirement or other conditions or restrictions imposed under that rule. In addition, the proposed books and records provision would specifically require a member firm subject to a Restricted Deposit Requirement to provide to the Department, upon its request, records that demonstrate the member firm's compliance with that requirement.

➢ Notice of Failure To Comply (Proposed Rule 4111(h))

FINRA also is proposing a requirement to address the situation when a member firm fails to comply with the obligations imposed pursuant to proposed Rule 4111. Under proposed Rule 4111(h), FINRA would be authorized to issue a notice pursuant to proposed Rule 9561 directing a member firm that is not in compliance with its Restricted Deposit Requirement, or with any conditions or restrictions imposed under Rule 4111, to suspend all or a portion of its business.

➢ Definitions (Proposed Rule 4111(i))

A complete list of defined terms used in proposed Rule 4111 appears in proposed Rule 4111(i).[40]

➢ Net Capital Treatment of the Deposits in the Restricted Deposit Account (Proposed Rule 4111.01)

Proposed Supplementary Material .01 would clarify that because of the restrictions on withdrawals from a Restricted Deposit Account, deposits in such an account cannot be readily converted to cash and therefore shall be deducted in determining the member's net capital under Exchange Act Rule 15c3–1[41] and FINRA Rule 4110.

➢ Compliance With Continuing Membership Application Rule (Proposed Rule 4111.02—Compliance with Rule 1017)

Proposed Supplementary Material .02 would clarify that nothing in proposed Rule 4111 would alter a member firm's obligations under Rule 1017 (Application for Approval of Change in Ownership, Control, or Business Operations). A member firm subject to proposed Rule 4111 would need to continue complying with the requirements of Rule 1017 and submit continuing membership applications as necessary.

➢ Examples of Conditions and Restrictions (Proposed Rule 4111.03)

In a change from *Regulatory Notice* 19–17, FINRA is proposing to add, in supplementary material to proposed Rule 4111, a non-exhaustive list of examples of conditions and restrictions that the Department could impose on Restricted Firms. FINRA believes that providing these examples will provide clarity about the Department's authority to impose conditions and restrictions without restricting the Department's flexibility to react and respond to different sources of risk. The non-exhaustive list of examples of conditions and restrictions includes: (1) Limitations on business expansions, mergers, consolidations or changes in control; (2) filing all advertising with FINRA's Department of Advertising Regulation; (3) imposing requirements on establishing and supervising offices; (4) requiring a compliance audit by a qualified, independent third party; (5) limiting business lines or product types offered; (6) limiting the opening of new customer accounts; (7) limiting approvals of registered persons entering into borrowing or lending arrangements with their customers; (8) requiring the member to impose specific conditions or limitations on, or to prohibit, registered persons' outside business activities of which the member has received notice pursuant to Rule 3270; and (9) requiring the member to prohibit or, as part of its supervision of approved private securities transactions for compensation under Rule 3280 or otherwise, impose specific conditions on associated persons' participation in private securities transactions of which the member has received notice pursuant to Rule 3280.

➢ Planned Review of Proposed Rule 4111

FINRA plans to conduct a review of proposed Rule 4111 after gaining sufficient experience under proposed Rule 4111. Among other things, FINRA would review whether the Preliminary Identification Metrics Thresholds remain targeted and effective at identifying member firms that pose higher risks.

Proposed Amendments to the Rule 9550 Series To Establish a New Expedited Proceeding To Implement the Requirements of Proposed Rule 4111

FINRA is proposing to establish a new expedited proceeding in proposed Rule 9561 (Procedures for Regulating Activities Under Rule 4111) that would allow member firms to request a prompt review of the Department's determinations under the Restricted Firm Obligations Rule and grant a right to challenge any of the ''Rule 4111 Requirements,'' including any Restricted Deposit Requirements, imposed.[42] The new expedited proceeding would govern how the Department provides notice of its determinations and afford affected member firms the right to seek a Hearing Officer's review of those determinations. The proposed expedited proceeding is similar in nature to FINRA's other expedited proceedings.

➢ Notices Under Proposed Rule 4111 (Proposed Rule 9561(a))

Proposed Rule 9561(a) would establish an expedited proceeding for the Department's determinations under proposed Rule 4111 to designate a member firm as a Restricted Firm and impose obligations on the member; and to deny a member's request to access all or part of its Restricted Deposit Requirement.

Proposed Rule 9561(a) would require the Department to serve a notice that provides its determination and the specific grounds and factual basis for the Department's action; states when the action will take effect; informs the member firm that it may file, pursuant to Rule 9559, a request for a hearing in an expedited proceeding within seven days after service of the notice; and explains the Hearing Officer's authority. The proposed rule also would provide that, if a member firm does not request a hearing, the notice of the Department's

[39] In the event of a liquidation of a Restricted Firm, funds or securities on deposit in the Restricted Deposit Account would be additional financial resources available for the Restricted Firm's trustee to distribute to those with claims against the Restricted Firm.

[40] *See* Exhibit 5.

[41] 17 CFR 240.15c3–1.

[42] Proposed Rule 9561(a)(1) would define the ''Rule 4111 Requirements'' to mean the requirements, conditions, or restrictions imposed by a Department determination under proposed Rule 4111.

determination will constitute final FINRA action.

Proposed Rule 9561(a) also would provide that any of the Rule 4111 Requirements imposed in a notice issued under proposed Rule 9561(a) are immediately effective. In general, a request for a hearing would not stay those requirements. There would be one partial exception: When a member firm requests review of a Department determination under proposed Rule 4111 that imposes a Restricted Deposit Requirement on the member for the first time, the member firm would be required to deposit, while the expedited proceeding was pending, the lesser of 25% of its Restricted Deposit Requirement or 25% of its average excess net capital over the prior year.

➢ Notice for Failure To Comply With the Proposed Rule 4111 Requirements (Proposed Rule 9561(b))

Proposed Rule 9561(b) would establish an expedited proceeding to address a member firm's failure to comply with any requirements imposed pursuant to proposed Rule 4111.

Proposed Rule 9561(b) would authorize the Department, after receiving authorization from FINRA's chief executive officer (''CEO''), or such other executive officer as the CEO may designate, to serve a notice stating that the member firm's failure to comply with the Rule 4111 Requirements, within seven days of service of the notice, will result in a suspension or cancellation of membership. The proposed rule would require that the notice identify the requirements with which the member firm is alleged to have not complied; include a statement of facts specifying the alleged failure; state when the action will take effect; explain what the member firm must do to avoid the suspension or cancellation; inform the member firm that it may file, pursuant to Rule 9559, a request for a hearing in an expedited proceeding within seven days after service of the notice; and explain the Hearing Officer's authority. The proposed rule also would provide that, if a member firm does not request a hearing, the suspension or cancellation will become effective seven days after service of the notice.

Proposed Rule 9561(b) also would provide that a member firm could file a request seeking termination of a suspension imposed pursuant to the rule, on the ground of full compliance with the notice or decision. The proposed rule would authorize the head of the Department to grant relief for good cause shown.

➢ Hearings (Proposed Amendments to the Hearing Procedures Rule)

If a member firm requests a hearing under proposed Rule 9561, the hearing would be subject to Rule 9559 (Hearing Procedures for Expedited Proceedings Under the Rule 9550 Series). FINRA is proposing several amendments to Rule 9559 that would be specific to hearings requested pursuant to proposed Rule 9561.

Hearings in expedited proceedings under proposed Rule 9561 would have processes that are similar to the hearings in most of FINRA's other expedited proceedings—including requirements for the parties' exchange of documents and exhibits, the time for conducting the hearing, evidence, the record of the hearing, the record of the proceeding, failures to appear, the timing and contents of the Hearing Officer's decision, the Hearing Officer's authority, and the authority of the NAC to call an expedited proceeding for review—and FINRA is proposing amendments to the Rule 9559 provisions that govern these processes to adapt them for expedited proceedings under proposed Rule 9561. A few features of the proposed amendments to Rule 9559 warrant emphasis or guidance.

• Hearing Officer's Authority (Proposed Amended Rule 9559(d) and (n))

Hearings in expedited proceedings under proposed Rule 9561 would be presided over by a Hearing Officer. The Hearing Officer's authority would differ depending on whether the hearing is in an action brought under proposed Rule 9561(a) (Notices Under Rule 4111) or 9561(b) (Notice for Failure to Comply with the Rule 4111 Requirements).

Proposed amended Rule 9559(n)(6) would provide that the Hearing Officer, in actions brought under proposed Rule 9561(a), may approve or withdraw any and all of the Rule 4111 Requirements, or remand the matter to the Department, but may not modify any of the Rule 4111 Requirements, or impose any other requirements or obligations available under proposed Rule 4111.

Proposed amended Rule 9559(n)(6) would authorize the Hearing Officer, in failure-to-comply actions under proposed Rule 9561(b), to approve or withdraw the suspension or cancellation of membership, and impose any other fitting sanction. Authorizing a Hearing Officer to impose any other fitting sanction is intended to provide a Hearing Officer with authority that is appropriate for responding to situations involving member firms that repeatedly fail to comply with an effective FINRA action under proposed Rule 4111.

• Timing Requirements

The proposed amendments to the Hearing Procedures Rule are intended to give member firms a prompt process for challenging a Department decision under proposed Rule 4111. Proposed amended Rule 9559(f) would require that a hearing in actions under proposed Rule 9561(a) be held within 30 days, and that a hearing in failure-to-comply actions under proposed Rule 9561(b) be held within 14 days, after the member firm requests a hearing.[43]

Proposed amended Rule 9559(o) would require the Hearing Officer, in all actions pursuant to proposed Rule 9561, to prepare a proposed written decision, and provide it to the NAC's Review Subcommittee, within 60 days of the date of the close of the hearing. Pursuant to Rule 9559(q), the Review Subcommittee could call the proceeding for review within 21 days after receipt of the proposed decision. As in most expedited proceedings, the timing of FINRA's final decision would then depend on whether or not the Review Subcommittee calls the matter for review.[44]

• Contents of the Decision

Proposed amended Rule 9559(p) would govern the contents of the Hearing Officer's decision. The proposed amendments would broaden Rule 9559(p)(6) to account for the kinds of obligations that could be imposed under proposed Rule 4111. Rule 9559(p) would otherwise remain the same. For example, Rule 9559(p) would continue to require that the Hearing Officer's decision include a statement setting forth the findings of fact with respect to any act or practice the respondent was alleged to have committed or omitted or any condition specified in the notice, the Hearing Officer's conclusions regarding the condition specified in the notice, and a statement in support of the disposition of the principal issues raised in the proceeding.

Additional guidance may be helpful, considering the different kinds of issues that may arise in an expedited proceeding pursuant to proposed Rule 9561. For example, in a request for a hearing of a Department determination that imposes a Restricted Deposit Requirement or other obligations under Rule 4111, the principal issues raised may include whether: (1) The member

[43] Proposed amendments to Rule 9559 contain other related timing requirements for proceedings pursuant to proposed Rule 9561.

[44] *See* FINRA Rule 9559(q).

firm should not be designated a Restricted Firm; (2) the Department incorrectly included disclosure events when calculating whether the member firm meets the Preliminary Criteria for Identification; (3) a Restricted Deposit Requirement would impose an undue financial burden on the member firm; or (4) the obligations imposed are inconsistent with the standards set forth in proposed Rule 4111(e). In a request for a hearing of a Department determination that denies a request to withdraw amounts from a Restricted Deposit Account, the principal issues raised may include whether the member firm or its Associated Persons have Covered Pending Arbitration Claims or unpaid arbitration awards and the nature of those claims or awards.

• No Collateral Attacks on Underlying Disclosure Events

In expedited proceedings pursuant to proposed Rule 9561(a) to review a Department determination under the Restricted Firm Obligations Rule, a member firm may sometimes seek to demonstrate that the Department included incorrectly disclosure events when calculating whether the member firm meets the Preliminary Criteria for Identification. When the member firm does so, however, it would not be permitted to collaterally attack the underlying merits of those final actions. An expedited proceeding under proposed Rule 9561 would not be the forum for attempting to re-litigate past final actions.[45]

If the Commission approves the proposed rule change, FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The effective date will be no later than 60 days following publication of the *Regulatory Notice* announcing Commission approval.[46]

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[47] 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. The proposed rule change is designed to protect investors and the public interest by strengthening the tools available to FINRA to address the risks posed by member firms with a significant history of misconduct, including firms at which individuals with a significant history of misconduct concentrate. The proposed rule would create strong measures of deterrence while a firm is designated as a Restricted Firm, limiting the potential for harm to the public. It also should create incentives for firms to change behaviors and activities, either to avoid being designated as a Restricted Firm or lose an existing Restricted Firm designation, to mitigate FINRA's concerns.

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.

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the regulatory need for the proposed rulemaking, its potential economic impacts, including anticipated benefits and costs, and the alternatives FINRA considered in assessing how to best meet its regulatory objectives.

Economic Impact Assessment

1. Regulatory Need

FINRA uses a number of measures to deter and discipline misconduct by firms and brokers, and continually strives to strengthen its oversight of the brokers and firms it regulates. These measures span across several FINRA programs, including review of new and continuing membership applications, risk monitoring of broker and firm activity, cycle and cause examinations, and enforcement and disciplinary actions.

As part of its efforts to monitor and deter misconduct, FINRA has adopted rules that impose supervisory obligations on firms to ensure they are appropriately supervising their brokers' activities. These rules require each firm to establish, maintain and enforce written procedures to supervise the types of business in which it engages and the activities of its associated persons that are reasonably designed to achieve compliance with applicable securities laws and regulations, and FINRA rules. Under this regulatory framework, FINRA also provides guidance to ensure consistency in interpretation of the rules and to further strengthen compliance across firms. As such, all firms play an important role in ensuring effective compliance with applicable securities laws and FINRA rules to prevent misconduct. This is consistent with the incentives of economic agents.[48]

Nonetheless, some firms do not effectively carry out these supervisory obligations to ensure compliance and they act in ways that could harm their customers—sometimes substantially. For example, recent academic studies find that some firms persistently employ brokers who engage in misconduct, and that misconduct can be concentrated at these firms. These studies also provide evidence of predictability of future disciplinary and other regulatory-related events for brokers and firms with a history of past similar events.[49] These patterns suggest that some firms may not be acting appropriately as a first line of defense to prevent customer harm. Further, some firms may take advantage of the fair-process protections afforded to them under the federal securities

[45] Attempts to collaterally attack final matters are also precluded in other FINRA proceedings. *Cf. Dep't of Enforcement* v. *Amundsen,* Complaint No. 2010021916601, 2012 FINRA Discip. LEXIS 54, at *21–24 (FINRA NAC Sept. 20, 2012) (rejecting respondent's attempt to collaterally attack a judgment that was required to be disclosed on Form U4), *aff'd,* Exchange Act Release No. 69406, 2013 SEC LEXIS 1148 (Apr. 18, 2013), *aff'd,* 575 F. App'x 1 (D.C. Cir. 2014); *Membership Continuance Application of Member Firm,* Application No. 20060058633, 2007 FINRA Discip. LEXIS 31, at *51 (July 2007) (holding, in a membership proceeding, that a firm may not address its and its FINOP's past disciplinary history by collaterally attacking those past violations) (citing *BFG Sec., Inc.,* 55 SEC. 276, 279 n.5 (2001)); *Jan Biesiadecki,* 53 SEC. 182, 185 (1997) (describing, in eligibility proceedings, FINRA's long-standing policy of prohibiting collateral attacks on underlying disqualifying events).

[46] FINRA notes that the proposed rule change would impact all member firms, including member firms that have elected to be treated as capital acquisition brokers (''CABs''), given that the CAB rule set incorporates the FINRA Rule 9550 Series by reference. In addition, FINRA is proposing to adopt CAB Rule 412, to reflect that a CAB would be subject to Rule 4111.

The proposed rule change would not impact, however, member firms that are funding portals. At this time, regulatory experience with funding portals is still at an early stage. The permissible business activities of funding portals are limited and, as such, it is not clear that funding portals present the corresponding risks that FINRA is seeking to address in the broker-dealer space. Moreover, developing relevant metrics and thresholds for funding portals would require a separate effort and analysis because, unlike broker-dealers, the Uniform Registration Forms do not apply to funding portals and their associated persons. Accordingly, FINRA is proposing to amend Funding Portal Rule 900(a) to add proposed Rule 9561 as a rule to which funding portal members would not be subject.

[47] 15 U.S.C. 78*o*–3(b)(6).

[48] *See, e.g.,* Roland Strausz, *Delegation of Monitoring in a Principal-Agent Relationship,* Rev. Econ. Stud. 64(3):337–57 (July 1997). The paper shows that in a standard principal-agent framework, the delegation of monitoring by the principal (*e.g.,* a regulator) to the agent (*e.g.,* a firm) can be economically efficient for both parties.

[49] *See supra* note 5.

laws and FINRA rules to forestall timely and appropriate regulatory actions, thereby limiting FINRA's ability to curb misconduct promptly. Without additional protections, the risk of potential customer harm may continue to exist at firms that fail to effectively carry out their supervisory obligations or are associated with a significant number of regulatory-related events. Further, even where harmed investors obtain arbitration awards, harm followed by recompense typically comes with some economic costs to customers and brokers, and firms may still fail to pay those awards. Unpaid arbitration awards harm successful customer claimants and may diminish investors' confidence in the arbitration process.[50]

To mitigate these risks, FINRA seeks additional authority to impose obligations on firms that pose these types of greater risk to their customers. The proposed Restricted Firm Obligations Rule would identify firms based upon a concentration of significant firm and broker events on their disclosure records that meet the proposed criteria and specified thresholds. Under the proposal, FINRA seeks to impose obligations on the operations and activities of the member and its associated persons that are necessary or appropriate to address the concerns indicated by the Preliminary Criteria for Identification and protect investors and the public interest.

2. Economic Baseline

The economic baseline used to evaluate the economic impacts of the proposed rules is the current regulatory framework, including FINRA rules relating to supervision, the membership application process, statutory disqualification proceedings and disciplinary proceedings that provide rules to deter and discipline misconduct by firms and brokers. This baseline serves as the primary point of comparison for assessing economic impacts of the proposed rules, including incremental benefits and costs.

The proposals are intended to apply to firms that pose far greater risks to their customers than other firms. One identifier of these types of firms is that they and their brokers generally have substantially more regulatory-related events on their records than do their peers.[51] Consistent with this, the proposed Restricted Firm Obligations Rule would specifically apply to firms that have far more Registered Person and Member Firm Events, or far higher concentrations of Registered Persons Associated with Previously Expelled Firms, compared to their peers.[52] Based on staff analysis of all firms registered with FINRA between 2013 and 2019, firms that would have met the Preliminary Criteria for Identification had on average four to nine times more Registered Person and Member Firm Events than peer firms at the time of identification. Specifically, the number of events per firm, for firms that would have met the Preliminary Criteria for Identification, ranged, on average, from 25–52 events during the Evaluation Period, compared to 4–5 events per firm for firms that would not have met the Preliminary Criteria for Identification. The median number of events per firm, for the firms that would have met the Preliminary Criteria for Identification, ranged from approximately 9–18 events, compared to zero events among other firms that would not have met the Preliminary Criteria for Identification.

Although disciplinary and regulatory-related events are one of the identifiers for firms posing higher risk, FINRA recognizes that firms posing higher risks do not always manifest themselves with greater disclosures on their records. These firms may be newer, have recently made changes in management, staff or approach, or simply may be more effective in avoiding regulatory marks.

3. Economic Impacts

a. Proposed Restricted Firm Obligations Rule

To estimate the number and types of firms that would meet the Preliminary Criteria for Identification, FINRA analyzed the categories of events and conditions associated with the proposed criteria for all firms during the 2013–2019 review period. For each year, FINRA determined the approximate number of firms that would have met the proposed criteria. The number of firms that would have met the proposed criteria during the review period serves as a reasonable estimate for the number of firms that would have been directly impacted by this proposal had it been in place at the time. This analysis indicates that there were 45–80 such firms at the end of each year during the review period, as shown in Exhibit 3a. These firms represent 1.3–2.0% of all firms registered with FINRA in any year during the review period. The population of firms identified by the proposed criteria reflects the distribution of firm size in the full population of registered firms. Approximately 88–94% of these firms were small, 4–12% were mid-size and 0–3% were large at the end of each year during the review period, as shown in Exhibit 3b.[53]

FINRA notes that the number of firms that would have met the proposed criteria during the review period have declined (by approximately 44%) from 80 firms in 2013 to 45 firms in 2019. This decline is associated with an overall decrease in the number of Registered Person and Member Firm Events and the number of firms associated with these events.[54] Specifically, the Registered Person and Member Firm Events have declined by 24% and the number of firms with one or more of these events has declined by 22% during the review period. However, the average number of events per firm identified by the proposed criteria has increased, suggesting that there may be an increase in concentration of events across a smaller set of firms that may pose greater risks to their customers. For example, the average number of Registered Person and Member Firm Events for the firms identified by the criteria has increased by 94% from 24 events per firm in 2013 to 47 events per firm in 2019. These trends over the 2013–2019 review period suggest that while many firms continue to improve their regulatory records over time, a small proportion of firms may continue to further engage in activities that pose greater risks to their customers, which the proposed rule is intended to address.

In developing the proposed Preliminary Criteria for Identification, FINRA paid significant attention to the impact of possible misidentification of firms, specifically, the economic trade-off between including firms that are less

[50] Investors may also file claims in courts or other dispute resolution forums. Successful claimants in these forums may face similar challenges associated with collecting awards or judgments.

[51] As discussed above, recent studies provide evidence of predictability of future regulatory-related events for brokers and firms with a history of past regulatory-related events. As a result, brokers and firms with a history of past regulatory-related events pose greater risk of future harm to their customers than other brokers and firms.

[52] For example, for each of the six Preliminary Identification Metrics, the Preliminary Identification Metrics Threshold was chosen to capture one to five percent of the firms with the highest number of events per registered broker or the highest concentrations of Registered Persons Associated with Previously Expelled Firms, in respective firm-size categories.

[53] FINRA defines a small firm as a member with at least one and no more than 150 registered persons, a mid-size firm as a member with at least 151 and no more than 499 registered persons, and a large firm as a member with 500 or more registered persons. *See* FINRA By-Laws, Article I.

[54] FINRA notes that part of the decline in the number of events and the firms that would have met the proposed criteria may be associated with an approximately 15% decline in the overall number of registered firms during the 2013–2019 review period.

likely to subsequently pose risk of harm to customers, and not including firms that are more likely to subsequently pose risk of harm to customers. There are costs associated with both types of misidentifications.[55] The proposed criteria, including the proposed numerical thresholds, aim to balance these economic trade-offs associated with over- and under-identification.[56] Further protection against misidentification would be provided by the proposed initial Department evaluation and the Consultation process.

➢ Anticipated Benefits

The proposal's primary benefit would be to reduce the risk and associated costs of possible future customer harm. This benefit would arise directly from additional restrictions placed on firms identified as Restricted Firms and resulting expected increased scrutiny by these firms on their brokers. Further, this benefit would also accrue indirectly from improvements in the compliance culture, both by firms that meet the proposed criteria and by firms that do not. For example, the proposal may create incentives for firms that meet the Preliminary Criteria for Identification to change activities and behaviors, to mitigate the Department's concerns. Similarly, the proposal may have a deterrent effect on firms that do not meet the Preliminary Criteria for Identification, particularly firms that may be close to meeting the proposed criteria. These firms may change behavior and enhance their compliance culture in ways that better protect their customers.

The proposal also may help address unpaid arbitration awards. Under the proposed rule, the Department may require a Restricted Firm to maintain a restricted deposit at a bank or a clearing firm that agrees not to permit withdrawals absent FINRA's approval. The amount of the Restricted Deposit Requirement would take into consideration, among other factors, the amount of any Covered Pending Arbitration Claims and unpaid arbitration awards against the member firm or its Associated Persons. Moreover, the proposed rule would have presumptions that the Department would: (a) Deny an application by a member firm or former member firm that was previously designated as a Restricted Firm for a withdrawal from the Restricted Deposit if the member firm, its Associated Persons who are owners or control persons, or the former member firm have any Covered Pending Arbitration Claims or unpaid arbitration awards, or if the member firm's Associated Persons have any Covered Pending Arbitration Claims or unpaid arbitration awards relating to arbitrations that involved conduct or alleged conduct that occurred while associated with the member firm; but (b) approve a former member firm's application for withdrawal if the former member firm commits in the manner specified by the Department to use the amount it seeks to withdraw from its Restricted Deposit to pay the former member firm's specified unpaid arbitration awards. Accordingly, the proposed rule could potentially create incentives for firms to pay unpaid arbitration awards against the firm or its Associated Persons, thereby alleviating, to some extent, harm to successful claimants and enhancing investor confidence in the arbitration process.[57]

To scope these potential benefits and assess the potential risk posed by firms that would meet the proposed Preliminary Criteria for Identification, FINRA evaluated the extent to which firms that would have met the criteria during 2013–2017 [58] (had the criteria existed) and their brokers were associated with ''new'' Registered Person and Member Firm Events after having met the proposed criteria. These ''new'' events correspond to events that were identified or occurred after the firm's identification, and do not include events that were pending at the time of identification and subsequently resolved in the years after identification. As shown in Exhibit 3c, FINRA estimates that there were 77 firms that would have met the Preliminary Criteria for Identification in 2013. These firms were associated with 1,552 ''new'' Registered Person and Member Firm Events that occurred after their identification, between 2014 and 2019. Exhibit 3c similarly shows the number of events associated with firms that would have met the Preliminary Criteria for Identification in 2014, 2015, 2016 and 2017. Across 2013–2017, there were 180 unique firms [59] that would have met the proposed Preliminary Criteria for Identification, and these firms were associated with a total of 2,995 Registered Person and Member Firm Events that occurred in the years after they met the proposed criteria.[60]

Exhibit 3c also shows the number of Registered Person and Member Firm Events for these firms compared to other firms. Specifically, FINRA calculated a factor which represents a multiple for the average number of events (on a per registered person basis) for firms that would have met the Preliminary Criteria for Identification relative to other firms of the same size that would not have met the Preliminary Criteria for Identification. For example, as shown in Exhibit 3c, the factor of 6.1x for 2013 indicates that firms meeting the Preliminary Criteria for Identification in 2013 had 6.1 times more new disclosure events (per registered person) in the years after identification (2014–2019) than other firms of the same size registered in 2013 that would not have met the Preliminary Criteria for Identification. Overall, this analysis demonstrates that firms that would have met the Preliminary Criteria for Identification during the 2013–2017 period had on average approximately 6–20 times more new disclosure events after their identification than other firms in the industry during the same period that would not have met the Preliminary Criteria for Identification.

➢ Anticipated Costs

The anticipated costs of this proposal would fall primarily upon firms that meet the Preliminary Criteria for Identification and that the Department deems to warrant further review after its initial evaluation. Although FINRA would perform the annual calculation and conduct an internal evaluation, firms may choose to expend effort to monitor whether they would meet the

[55] For example, subjecting firms that are less likely to pose a risk to customers to the proposed Restricted Deposit Requirement or other obligations would impose additional and unwarranted costs on these firms, their brokers and their customers.

[56] In order to evaluate the effectiveness of the proposed criteria at identifying firms that pose greater risks, FINRA examined the overlap between the firms that would have met the Preliminary Criteria for Identification each year during the review period and the firms that were subsequently expelled, associated with unpaid awards, or identified by Department staff as suitable candidates for additional obligations. Finally, as discussed below, FINRA also examined disclosure events associated with firms that would have met the Preliminary Criteria for Identification each year during the review period, subsequent to meeting the criteria, to assess the extent of risk posed by these firms.

[57] Further, as discussed above, the Department would consider a member firm's and its Associated Persons' unpaid arbitration awards as one of the factors in determining the amount of the Restricted Deposit Requirement. As a result, there would be additional incentives to pay unpaid arbitration awards.

[58] This analysis examines firms that would have met the Preliminary Criteria for Identification from 2013 until 2017 (instead of the 2013–2019 review period) to allow sufficient time for the ''new'' events to resolve in the post-identification period.

[59] Certain firms would have met the criteria in multiple years during the review period. The 180 firms discussed in the text correspond to the unique number of firms that would have met the criteria in one or more years during the review period.

[60] Specifically, FINRA examined and counted all Registered Person and Member Firm Events that occurred any time after the firms were identified until December 31, 2019.

Preliminary Criteria for Identification, and incur associated costs, at their own discretion. To the extent that a firm deemed to warrant further review under proposed Rule 4111 chooses to seek to rebut the presumption that it is a Restricted Firm subject to the maximum Restricted Deposit Requirement, it would incur costs associated with collecting and providing information to FINRA. For example, these firms may provide information on any disclosure events that may be duplicative or not sales-practice related. These firms may also provide information on any undue significant financial hardship that would result from a maximum Restricted Deposit Requirement. Likewise, a firm availing itself of the one-time staffing reduction opportunity incurs the separation costs, along with the potential for lost future revenues.

In addition, firms subject to a Restricted Deposit Requirement or other obligations would incur costs associated with these additional obligations. These would include, for example, costs associated with setting up the Restricted Deposit Account and ongoing compliance costs associated with maintaining the account. Further, as a result of restrictions on the use of cash or qualified securities in the deposit account or other restrictions on the firm's activities, the firm may lose economic opportunities, and its customers may lose the benefits associated with the provision of these services.

Similarly, a firm required to apply heightened supervision to its brokers would incur implementation and ongoing costs associated with its heightened supervision plan.[61] Firms that meet the Preliminary Criteria for Identification also may incur costs associated with enhancing their compliance culture, including possibly terminating registered persons with a significant number of disclosure events—through exercising the one-time staffing reduction option under proposed Rule 4111 or otherwise—and reassigning the responsibilities of these individuals to other registered persons. Finally, there may be indirect costs, including greater difficulty or increased cost associated with maintaining a clearing arrangement, loss of trading partners, or similar impairments where third parties can determine that a firm meets the proposed Preliminary Criteria for Identification or has been deemed to be a Restricted Firm.

Firms that do not meet the proposed Preliminary Criteria for Identification, particularly ones that understand they are close to meeting the proposed criteria, also may incur costs associated with enhancing their compliance culture or making other changes in order to avoid meeting the proposed criteria in the future. These costs may include terminating registered persons with disciplinary records, replacing them with existing or new hires, enhancing compliance policies and procedures, and improving supervision of registered persons. Finally, registered persons with significant number of disciplinary or other disclosure events on their records may find it difficult to retain employment, or get employed by new firms, particularly where those firms and their associated registered persons already have disciplinary records. Similarly, firms meeting the proposed criteria or those close to meeting the proposed criteria may find it difficult to hire registered persons with disclosure events. FINRA notes, however, that the anticipated economic impacts on firms hiring and registered persons seeking employment would likely be limited to a small proportion of registered persons and member firms.[62]

➢ Other Economic Impacts

FINRA also has considered the possibility that, in some cases, this proposal may impose restrictions on brokers' and firms' activities that are less likely to subsequently harm their customers. In such cases, these brokers and firms may lose economic opportunities or find it difficult to retain brokers or customers. FINRA believes that the proposal mitigates such risks by requiring an initial layer of Departmental review, and providing affected firms an opportunity to engage in a Consultation with the Department and request a review of the Department's determination in an expedited proceeding.

FINRA also considered that some firms may consider not reporting, underreporting, or failing to file timely, required disclosures on Uniform Registration Forms in an effort to avoid costs associated with the proposals. However, this potential impact is mitigated because many events are reported by regulators or in separate public notices by third parties and, as a result, FINRA can monitor for these unreported events. Further, failing to timely update Uniform Registration Forms is a violation of FINRA rules and can result in fines and penalties, thereby serving as a deterrent for underreporting, misreporting and failing to file timely required disclosures.

Considering that the proposed criteria are based on a firm's experience relative to its similarly sized peers, FINRA does not believe that the proposed criteria impose costs on competition between firms of different sizes. Further, because FINRA would perform the annual calculation to determine the firms that meet the Preliminary Criteria for Identification, the costs a firm incurs to monitor its status in relation to the proposed criteria would be discretionary and not likely create any competitive disadvantage based on firm size. Although the proposed rule would not impose these monitoring costs, FINRA would provide transparency around how the Preliminary Criteria for Identification are calculated and appropriate guidance to assist firms seeking to monitor their status. Similarly, FINRA does not anticipate that the proposed Restricted Firm Obligations Rule, including the Restricted Deposit Requirement or any required conditions and restrictions, would create competitive disadvantages across firms of different sizes. This is, in part, because FINRA would consider the number of offices and registered persons, among other factors, when determining the appropriate maximum Restricted Deposit Requirement or any conditions and restrictions, to ensure that the obligations are appropriately tailored to the firm's business model but do not significantly undermine the continued financial stability and operational capability of the firm as an ongoing enterprise over the ensuing 12 months.

As discussed above, FINRA would exercise some discretion in determining the maximum Restricted Deposit Requirement and tailor it to the size, operations and financial conditions of the firm, among other factors. This approach is intended to align with FINRA's objective to have the specific financial obligation be significant enough to change a Restricted Firm's

[61] These costs would likely vary significantly across firms. Costs would depend on the specific obligations imposed specific to the firm and its business model. In addition, costs could escalate if a heightened supervision plan applied to brokers that serve as principals, executive managers, owners, or in other senior capacities. Such plans may entail reassignments of responsibilities, restructuring within senior management and leadership, and more complex oversight and governance approaches.

[62] For example, during the 2013 to 2019 review period, only one to two percent of the registered persons had any qualifying events in their regulatory records, which represents the most conservative estimate of the set of registered persons who might be impacted by the proposed rule. Further, the vast majority of member firms, approximately 98%, would likely be able to employ most of the individuals seeking employment in the industry—including ones who have some disclosures—without coming close to meeting the Preliminary Criteria for Identification.

behavior but not so burdensome that it would indirectly force it out of business. In determining the specific maximum Restricted Deposit Requirement, FINRA would consider a range of factors, including the nature of the firm's operations and activities, revenues, commissions, assets, liabilities, expenses, net capital, the number of offices and registered persons, the nature of the disclosure events counted in the numeric thresholds, insurance coverage for customer arbitration awards or settlements, concerns raised during FINRA exams, and the amount of any of the firm's or its Associated Persons' ''Covered Pending Arbitration Claims'' or unpaid arbitration awards. In developing the proposal, FINRA considered the possibility of having a transparent formula, based on some of these factors, to determine a maximum Restricted Deposit Requirement. However, as discussed in more detail below, given the range of relevant factors and differences in firms' business models, operations, and financial conditions, FINRA decided not to propose a uniform, formulaic approach across all firms.

In developing the proposal, FINRA also considered the possibility that the size of the maximum Restricted Deposit Requirement may be too burdensome for the firms, and could undermine their financial stability and operational capability. FINRA believes that these risks are mitigated by providing affected firms an opportunity to engage in a Consultation process with FINRA and propose a lesser Restricted Deposit Requirement or restrictions or conditions on their operations. Further, as discussed above, Restricted Firms would have the opportunity to request a review of the Department's determination in an expedited proceeding.

b. Proposed Expedited Proceeding Rule

When FINRA imposes obligations on a firm pursuant to the proposed Restricted Firm Obligations Rule, the firm may experience significant limitations to its business activities and incur direct and indirect costs associated with the obligations imposed. The proposed Expedited Proceeding Rule would, in general, require that these obligations apply immediately, even during the pendency of any appeal.

The proposed rule would be associated with investor protection benefits through the impact of the no-stay provision in proposed Rule 9561(a)(4). Under the proposal, obligations imposed by the Department would be effective immediately, except that a firm that is subject to a Restricted Deposit Requirement under proposed Rule 4111 and requests a hearing would be required to make only a partial deposit while the hearing is pending. This would reduce the risk of investor harm during the pendency of a hearing. Similarly, the no-stay provision may limit hearing requests by firms that seek to use them only as a way to forestall FINRA obligations.

The benefit of the proposed rule accruing to firms would be to permit firms to appeal FINRA's determinations (both to request prompt review of obligations imposed or of determinations for failure to comply) in an expedited proceeding, thereby reducing undue costs where firms may have been misidentified or where the obligations imposed are not necessary or appropriate to address the concerns indicated by the Preliminary Criteria for Identification and protect investors and the public interest. For example, the proposed rule is anticipated to reduce any undue costs by the proceeding's expedited nature. Similarly, the proposed rule's time deadlines may also reduce the costs of the proceedings, in certain cases.

The costs would be borne by firms that choose to seek review via the proposed expedited proceeding, and these costs can be measured relative to a standard proceeding. These firms would incur costs associated with provisions and procedures specific to this proposed rule, including the provision that the obligations imposed would not be stayed.[63] This would include the obligations imposed under the proposed rule, including the Restricted Deposit Requirement, and the requirement that the firm, upon the Department's request, provide evidence of its compliance with these obligations. However, the extent of the costs associated with the Restricted Deposit Requirement would be mitigated by the expedited nature of the proceeding and by the provision that would require a firm, during the pendency of an expedited hearing process, to maintain only a partial deposit requirement.

As with the other proposals, FINRA does not anticipate that the proposed rule would have differential competitive effects based on firm size or other criteria. The costs and benefits are anticipated to apply to all firms that request a hearing in an expedited proceeding.

4. Alternatives Considered

FINRA recognizes that the design and implementation of the rule proposals may impose direct and indirect costs on a variety of stakeholders, including firms, brokers, regulators, investors and the public. Accordingly, in developing its rule proposals, FINRA seeks to identify ways to enhance the efficiency and effectiveness of the proposed rules while maintaining their regulatory objectives. For example, FINRA considered several alternatives to addressing the risks posed by firms and their brokers that have a history of misconduct, including alternative approaches and alternative specifications to the numeric threshold based-approach and the Restricted Deposit Requirement.

a. Alternative to the Proposed Numeric Threshold-Based Approach

In addition to the proposed approach based on numeric thresholds, FINRA considered an approach similar to the Investment Industry Regulatory Organization of Canada's (IIROC) ''terms and conditions'' rule, IIROC Consolidated Rule 9208, that would allow FINRA to identify a limited number of firms with significant compliance failures and impose on them appropriate terms and conditions to ensure their continuing compliance with the securities laws, the rules thereunder, and FINRA rules.[64] FINRA considered and evaluated the economic impacts of such a terms and conditions rule relative to proposed Rule 4111.

Compared to proposed Rule 4111, a terms and conditions rule would provide FINRA with greater flexibility in identifying firms that should be subject to additional obligations. This greater flexibility could help better target its application and reduce misidentification by allowing FINRA to leverage non-public information, including regulatory insights collected as part of its monitoring and examination programs, in identifying firms that pose the greatest risk. Further, under a terms and conditions rule, FINRA could quickly update its identification of firms based on emerging risk patterns, to ensure that the rule continues to be effective at addressing firms that presently pose the greatest risk. This flexibility could

[63] The effect of the no-stay provision is that imposed obligations would apply immediately, even during the pendency of any hearing request. As a result, the no-stay provision would impose direct costs on misidentified firms or firms for which the obligations imposed are not necessary or appropriate.

[64] IIROC Consolidated Rule 9208 permits IIROC to impose terms and conditions on an IIROC Dealer Member's membership when IIROC considers these terms and conditions appropriate to ensure the member's continuing compliance with IIROC requirements.

mitigate the risk that the criteria and thresholds in proposed Rule 4111 no longer identify the appropriate firms.

Further, as discussed above, the identification criteria in proposed Rule 4111 may not identify all the firms that pose material risk to their customers, such as firms that may act to stay just below the proposed criteria and thresholds by any means, including misreporting or underreporting disclosure events. The absence of a set identification criteria in a terms and conditions rule would make it more difficult for firms to evade the identification criteria and thus could provide greater investor protections.+

At the same time, a terms and conditions rule may have certain disadvantages relative to proposed Rule 4111. For example, a benefit of proposed Rule 4111 is the deterrent effect it may have on firms that do not meet the proposed Preliminary Criteria for Identification, particularly firms that may be close to meeting the criteria. These firms may change behavior and enhance their compliance culture in ways that could better protect their customers. By comparison, under a terms and conditions rule, in the absence of transparent criteria, firms would have to assess FINRA's view of the significance of repeated exam findings to determine whether to change their conduct to avoid potential terms and conditions.

Although FINRA has considered, and will continue to explore, this alternative, it is not proposing a terms and conditions rule at this time.

b. Alternative Specifications for the Proposed Numeric Threshold-Based Approach

FINRA also considered several alternatives to the numerical thresholds and conditions for the Preliminary Criteria for Identification. In determining the proposed criteria, FINRA focused significant attention on the economic trade-off between incorrect identification of firms that may not subsequently pose risk of harm to their customers, and not including firms that may subsequently pose risk of harm to customers. FINRA also considered three key factors: (1) The different categories of reported disclosure events and metrics, including the Expelled Firm Association Metric; (2) the counting criteria for the number of reported events or conditions; and (3) the time period over which the events or conditions are counted. FINRA considered several alternatives for each of these three factors.

➢ Alternatives Associated With the Categories of Disclosure Events and Metrics

In determining the different types of disclosure events, FINRA considered all categories of disclosure events reported on the Uniform Registration Forms, including the financial disclosures. FINRA decided to exclude financial disclosures because while financial events, such as bankruptcies, civil bonds, or judgments and liens, may be of interest to investors in evaluating whether or not to engage a broker or a firm, these types of events by themselves are not evidence of customer harm.

In developing the Preliminary Criteria for Identification, FINRA also considered whether pending criminal, internal review, judicial and regulatory events should be excluded from the threshold test. Pending matters are often associated with an emerging pattern of customer harm and capture timely information of potential ongoing or recent misconduct. However, pending matters may include pending regulatory investigations and criminal proceedings that do not result in a finding.[65] FINRA evaluated the impact of eliminating pending matters from the Preliminary Criteria for Identification. Specifically, FINRA identified the firms that would no longer meet the proposed criteria (had the criteria existed) during the evaluation period if pending-events categories were eliminated from the criteria, and examined the extent to which such firms were associated with ''new'' Registered Person and Member Firm Events. As shown in Exhibit 3d, FINRA estimates that these firms had on average approximately 8.0–13.1 times more new disclosure events than other firms in the industry during the same period that would not have met the Preliminary Criteria for Identification.[66] Accordingly, based on this review and other validations, FINRA decided to include pending matters in the proposed criteria because they are critical to identifying firms that pose greater risks to their customers.

As with other categories, the proposed Preliminary Identification Metrics Thresholds for the relevant Preliminary Identification Metrics, including the Registered Person Pending Event Metric and the Member Firm Pending Event Metric, are intended to capture firms that are on the far tail of the distributions. Thus, firms meeting these thresholds have far more pending matters on their records than other firms in the industry that do not meet these thresholds. Nonetheless, FINRA recognizes that pending matters include disclosure events that may remain unresolved or that may subsequently be dismissed or concluded with no adverse action because they lack merit or suitable evidence.[67] In order to ensure that a firm does not meet the Preliminary Criteria for Identification solely because of pending matters, FINRA has proposed the conditions that, to meet the criteria, the firm must meet or exceed at least two of the six Preliminary Identification Metrics Thresholds, and at least one of the thresholds for the Registered Person Adjudicated Event Metric, Member Firm Adjudicated Event Metric, or Expelled Firm Association Metric.

In developing the Preliminary Criteria for Identification, FINRA also considered alternatives to the Expelled Firm Association Metric. For example, in *Regulatory Notice* 19–17, FINRA initially proposed the metric to be based on all registered persons who were previously associated with one or more previously expelled firms, at any time in their career and irrespective of their duration of association at the previously expelled firm. FINRA subsequently narrowed the Expelled Firm Association Metric by only including registered persons who were registered with a previously expelled firm within the prior five years (*i.e.,* whose registration with a previously expelled firm terminated during the prior five years) and who were registered with the expelled firm for at least one year. FINRA selected this formulation to analyze because the five-year lookback is consistent with the lookback periods for the other proposed metrics in the proposal and, based on staff experience,

[65] As discussed in more detail below, several commenters expressed concerns about including pending and un-adjudicated events in the Preliminary Criteria for Identification. Commenters suggested that pending events are often associated with frivolous cases and that many pending regulatory investigations and criminal proceedings are discontinued without action.

[66] In assessing the impact of removing pending events from the Preliminary Criteria for Identification and restricting the criteria solely to final events, FINRA also examined the number of firms that would have met or exceeded at least one Preliminary Identification Metrics Threshold in the Registered Person Adjudicated Events, Member Firm Adjudicated Events, or Registered Persons Associated with Expelled Firms categories, during the relevant period. This analysis showed that the number of firms identified by this alternative criteria would increase from 45–80 firms to 131–196 firms, each year, during the review period. Similarly, FINRA estimates the number of firms that would have met or exceeded at least two thresholds within these categories to be 32–57 firms, each year, during the review period.

[67] For example, customers may file complaints that are false or erroneous and such complaints may subsequently be withdrawn by the customers or get dismissed by arbitrators or judges.

FINRA believes that individuals who are more recently associated with previously expelled firms (*e.g.,* in the last five years) and have longer tenures at expelled firms (*e.g.,* a year or more, instead of a shorter employment duration) generally pose higher risk than other individuals.

In developing the proposal, FINRA conducted several validations on the firms meeting the criteria, including the proposed Expelled Firm Association Metric, by reviewing the extent to which firms identified during 2013–2017 (had the criteria existed) were subsequently expelled, associated with unpaid awards, or identified by the Department as suitable candidates for additional obligations. As discussed above, FINRA also evaluated the extent to which firms that would have met the criteria during 2013–2017 (had the criteria existed) and their brokers were associated with ''new'' Registered Person and Member Firm Events after having met the criteria. As shown in Exhibit 3c, FINRA estimates that the identified firms had on average approximately 6.1–19.9 times more new disclosure events after their identification than other firms in the industry during the same period that would not have met the Preliminary Criteria for Identification. Based on staff review and validations, FINRA believes that the proposed Expelled Firm Association Metric preserves the usefulness of the Preliminary Criteria for Identification (as originally proposed in *Regulatory Notice* 19–17) and continues to identify firms that pose greater risks to their customers.

➢ Alternatives Associated With the Counting Criteria for the Proposed Criteria and Metrics

FINRA considered a range of alternative counting criteria for the Preliminary Criteria for Identification. For example, FINRA considered whether the Preliminary Criteria for Identification should be based on firms meeting two or more Preliminary Identification Metrics Thresholds, or whether the number of required thresholds should be decreased or increased. Decreasing the number of required thresholds from two to one would increase the number of firms that would have met the Preliminary Criteria for Identification during the review period from 45–80 firms to 155–217 firms, each year. Alternatively, increasing the number of required thresholds from two to three would decrease the number of firms that would have met the Preliminary Criteria for Identification from 45–80 firms to 11–20 firms, each year. FINRA reviewed the list of firms identified under these alternative counting criteria and examined the extent to which they included firms that were subsequently expelled, associated with unpaid awards, or identified by the Department as suitable candidates for additional obligations. FINRA also paid particular attention to firms that would have been identified by these alternative criteria but subsequently were not associated with high-risk activity, as well as firms that would not have been identified by these alternatives that were associated with high-risk events. Based on this review, FINRA believes that the proposed approach—meeting two or more of the Preliminary Identification Metrics Thresholds—more appropriately balances these trade-offs between misidentifications than the alternative criteria.

➢ Alternatives Associated With the Time Period Over Which the Metrics Are Calculated

The proposed Preliminary Identification Metrics are based on two different time periods over which different categories of events and conditions are counted (''lookback periods''). Pending events, including the Registered Person Pending Events and the Member Firm Pending Events categories, are counted in the Preliminary Identification Metrics only if they are pending as of the Evaluation Date. Adjudicated events, including the Registered Person Adjudicated Events and the Member Firm Adjudicated Events categories, and Registered Persons Associated with Previously Expelled Firms are counted in the Preliminary Identification Metrics over a five-year lookback period.[68]

In developing the proposal, FINRA considered alternative criteria for the time period over which the disclosure events or conditions are counted. For example, FINRA considered whether adjudicated events should be counted over the individual's or firm's entire reporting period or counted over a more recent period. Based on its experience, FINRA believes that more recent events (*e.g.,* events occurring in the last five years) generally pose a higher level of possible future risk to customers than other events. Further, counting events over an individual's or firm's entire reporting period would imply that brokers and firms would always be included in the Preliminary Identification Metrics for adjudicated events, even if they subsequently worked without being associated with any future adjudicated events. Accordingly, FINRA decided to include adjudicated events only in the more recent period (*i.e.,* a five-year period).[69]

Similarly, FINRA also considered alternative limits on the time periods over which components of the Expelled Firm Association Metric would be calculated. For example, FINRA considered alternative metrics based on only firms that have been expelled within three to five years prior to the Evaluation Date. Further, FINRA considered alternatives where the individual broker's association with the previously expelled firm was within a five-year window around the firm's expulsion. In evaluating these alternatives, FINRA recalculated the underlying thresholds to capture firms that are on the far tail of the distribution for these alternative metrics.[70] As with other alternatives, FINRA conducted several validations on alternative specifications of time periods for calculating the Expelled Firm Association Metric. These validations included reviewing the extent to which firms identified by alternative specifications of the proposed criteria were associated with ''new'' events after identification, subsequently expelled or associated with unpaid awards, or were identified by the Department as suitable candidates for additional obligations. Based on these validations, FINRA selected the proposed five-year period for calculating the Expelled Firm Association Metric as the alternative specifications did not result in any material change to the proposed criteria's ability to identify firms that pose greater risk of customer harm.[71]

c. Alternatives to the Restricted Deposit Requirement

In developing the proposal, FINRA considered alternative approaches to the Restricted Deposit Requirement. For example, FINRA considered increasing the capital requirements on identified firms, in lieu of the Restricted Deposit Requirement. A net capital approach would provide the identified firms

[68] Registered Persons In-Scope include all persons registered with the firm for one or more days within the one year prior to the Evaluation Date.

[69] This also is consistent with the time period used for counting ''specified risk events'' in SR–FINRA–2020–011.

[70] These alternatives would have identified approximately the same number of firms as meeting the Preliminary Criteria for Identification, during the review period.

[71] For example, as discussed above, FINRA estimates that the firms identified by the proposed criteria (based on a five-year period for calculating the Expelled Firm Association Metric) had on average approximately 6.1–19.9 times more new disclosure events after their identification than other firms in the industry during the same period that would not have met the proposed criteria.

greater flexibility and control over the assets. These firms would be able to use the assets for cash flow and operating expenses. As a result, an additional net capital charge would be associated with lower direct and indirect costs to these firms. However, there are several drawbacks with respect to economic incentives and anticipated impacts to relying upon a net capital approach as a tool for addressing the risks posed by firms with a significant history of misconduct. For example, the firm assets that would be maintained pursuant to an increased net capital requirement would not be deposited into a separate restricted account and may be fungible with other firm assets. As a result, these assets could be withdrawn by the identified firms at any time and these firms could employ the capital during the pendency of the restriction period. This suggests that the deterrent effect of an increased net capital approach would be much lower on a dollar-for-dollar basis than the proposed Restricted Deposit Requirement. An increased net capital approach also may not be sufficiently impactful in providing incentives to change firm behavior if a Restricted Firm already maintains substantial excess net capital. Further, considering that the identified firms could withdraw their assets at any time under a net capital approach, FINRA would not be able to ensure that any funds would be available for satisfying unpaid arbitration awards. In light of these considerations, FINRA decided to propose a Restricted Deposit Requirement approach, rather than changes to the capital requirements on identified firms.

FINRA also considered whether the Restricted Deposit Requirement amount should be based on a formula or include a cap in order to provide greater transparency to the member firms. To assess the feasibility of a strict formula or cap in setting the Restricted Deposit Requirement, FINRA assessed the financial condition of the firms that would have been identified by the Preliminary Criteria for Identification in 2019 (if the criteria had existed) and found significant variation across firms. These variations existed even across firms within the same size category. For example, FINRA found that the highest firm's revenues were approximately 1,750 times that of the firm with the lowest revenue when standardized by the number of registered persons at the firm. Within firm size categories, the corresponding difference in revenues per registered person was as high as over 80 times. Similarly, there was significant variation in the reported cash and ownership equity across these firms. The highest firm's excess net capital was over 3,500 times that of the firm with the lowest excess net capital (standardized per registered person).[72] The firm reporting the highest ownership equity was over 2,300 times that of the lowest firm's ownership equity (standardized per registered person). Further, firms' awards and settlements appear to be unrelated to their financial condition. For example, FINRA estimates that over 20% of the identified firms with high awards and settlement amounts have low or medium revenues (on a per registered person basis) or high revenues and low or medium awards and settlement amounts.[73] Thus there appears to be no consistent relationship between firm size, and basic metrics of the financial condition of the firm, and potential obligations to harmed customers. Given these significant variations in quantitative factors and the qualitative nature of some of the factors for consideration (*e.g.,* concerns raised during FINRA exams), FINRA decided to maintain the Department's discretion for determining the Restricted Deposit Requirement, instead of proposing a formula or a cap. Additionally, FINRA believes that if the proposal were to include a precise formula, it may undermine the effectiveness of the rule by providing an opportunity for firms to take actions to minimize the expected restricted deposit.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The proposed rule change was published for comment in *Regulatory Notice* 19–17 (May 2019). Thirty-two comments were received in response to the *Regulatory Notice.*[74] Exhibit 2a is a copy of the *Regulatory Notice.* Exhibit 2b is a list of commenters. Exhibit 2c contains copies of the comment letters received in response to the *Regulatory Notice.* Of the 32 comment letters received, 11 were generally in favor of the proposed rule change, and 18 were generally opposed.

FINRA has considered the comments received. In light of some of those comments, FINRA has made some modifications to the proposal. The comments and FINRA's responses are set forth in detail below.

1. General Support for the Proposal

Several commenters expressed general support for the proposed rule changes in *Regulatory Notice* 19–17.[75] For example, NASAA commended FINRA's attempt to strategically identify, and more strongly regulate, the limited number of member firms with histories of regulatory noncompliance, and stated that the proposal should increase investor protection while imposing minimal burdens on the brokerage industry. Massachusetts called the proposal a positive step toward protecting investors from the riskiest corners of the brokerage industry, and asserted that the proposal rightly places the burden of investor protection on the firms that hire bad brokers and ensures that investors have meaningful recourse when harmed. CAI likewise expressed support for how the proposal would enhance customer protection by imposing additional obligations on a targeted group of firms. SIFMA supported how the proposal fits into FINRA's continuing efforts to help ensure that arbitration claims, awards, and settlements are paid in full. Cetera supported both the concept and manner in which FINRA has approached this effort. Cambridge agreed that an objective data assessment coupled with a comprehensive and transparent review of that data—which is the general structure of the proposed Restricted Firm Obligations Rule—will aid FINRA in identifying those high risk member firms and registered persons contemplated by this proposal.

2. General Opposition to the Proposal

Several commenters generally opposed proposed Rule 4111, on a variety of grounds. For example, several commenters wrote that the proposal would disproportionately affect small firms or reflected an attempt to put small firms out of business.[76] PIRC, however, characterized industry

[72] *See* Exhibit 3e, which reflects the firms that would have met the Preliminary Criteria for Identification in 2019, had the criteria existed.

[73] For purposes of this Form 19b–4, ''high'' arbitration awards, settlement amounts and revenues means the top tercile (above 66th percentile) of these awards, settlements and revenues among firms that would have met the proposed criteria, and ''medium'' and ''low'' arbitration awards, settlement amounts and revenues means the middle tercile (33rd–66th percentile) and bottom tercile (below the 33rd percentile). *See* Exhibit 3f, which reflects the firms meeting the Preliminary Criteria for Identification in 2019.

[74] All references to commenters are to the comment letters as listed in Exhibit 2b.

[75] CAI, Cambridge, Cetera, FSI, Massachusetts, MIRC, NASAA, PIABA, PIRC, SIFMA, St. John's SOL. Supportive commenters also suggested ways in which the proposal could be modified or enhanced, which are discussed in more detail below.

[76] Brooklight, Colorado FSC, Dempsey, FSI, IBN, Joseph Stone, Luxor, McNally, Moss & Gilmore, Westpark.

objections that the proposed rule would disproportionately affect small firms as unwarranted noting that the rule accounts for different firm sizes in its threshold calculations. Each specific numeric threshold in the Preliminary Identification Metrics Thresholds grid (proposed Rule 4111(i)(11)) represents an outlier with respect to similarly sized peers. Moreover, the process of determining a Restricted Deposit Requirement would require the Department to consider several factors that relate to firm size and a parameter directly influenced by firm size.[77] Thus, while the revised proposal includes several modifications that will lessen some of the original proposal's burdens on all firms, the modifications are not specific to small firms.

Some commenters generally opposed the proposal on the basis of its potential adverse impacts on individuals.[78] For example, some commenters contended that many terminated individuals would have to uproot their lives and be unable to find a new broker-dealer.[79] Brooklight commented that innocent representatives who associated with a firm expelled for firm-level issues would be marked with a ''scarlet letter'' that could end their careers. Westpark commented that the proposed rule would make it financially untenable for small firms to employ brokers with certain levels of disclosures, essentially making them unemployable. HLBS commented that the proposed rule will allow FINRA to grossly intrude on member firms' recruiting and termination decisions. Some commenters expressed concern that the proposal would unfairly affect some persons who previously worked at disciplined firms and persons with any regulatory incidents regardless of their intent.[80]

FINRA notes, however, that between 2013 and 2019, only one to two percent of registered persons in any year had any qualifying events in their regulatory records, which represents the most conservative estimate of the set of brokers who might be associated with the proposed rule. Further, approximately 98% of member firms would be able to employ individuals seeking employment in the industry—including ones who have some disclosures and ones who were terminated by Restricted Firms—without meeting the Preliminary Criteria for Identification. Moreover, under a separately proposed rule, a member firm could register an individual who has only one ''specified risk event'' in their record without having to request a materiality consultation.[81]

For these reasons, FINRA is not proposing to revise proposed Rule 4111 to address these comments, except to narrow the scope of the Expelled Firm Association Metric. FINRA recognizes that proposed Rule 4111 could result in some firms declining to employ persons who have associated with a firm that has been expelled, even when it would not cause the firm to meet the Preliminary Criteria for Identification. FINRA does not believe this concern—which is similar to how some firms may respond to FINRA's ''Taping Rule'' [82]—warrants removing the Expelled Firm Association Metric from the Preliminary Criteria for Identification. Nevertheless, as explained more below, FINRA has narrowed the Expelled Firm Association Metric, to narrow its impact on individuals.

Westpark commented that the proposal is inconsistent with Section 15(b)(6) of the Exchange Act, which requires that FINRA rules not be designed to permit unfair discrimination between brokers or dealers, and Section 15A(b)(9) of the Exchange Act, which requires that FINRA rules not impose any burden on competition not necessary or appropriate in furtherance of the Exchange Act. Proposed Rule 4111, however, will allow FINRA to impose obligations only on the limited number of member firms that pose substantially higher risks to investors compared to their similarly sized peers, and only after a multi-step process that has numerous procedural protections, for the purpose of protecting investors and the public interest. Therefore, FINRA believes the proposal is an appropriate means of protecting investors and the public interest, and is not unfair.[83]

Several commenters predicted that, for a variety of reasons, the proposal will not achieve its intended goals [84] or commented that the proposal is insufficient.[85] For example: (1) Some question the underlying premise of using disclosure data to predict future customer harm; [86] (2) Rockfleet suggested that when a Restricted Deposit Requirement would essentially shut a firm down, the firm would likely terminate its membership and ''leav[e] FINRA in exactly the position it is seeking to avoid''; (3) Joseph Stone commented that firms that dilute their concentration of brokers that meet the threshold criteria can still pose risks, and that the proposal will ''force firm management to push quality and compliant representatives out of their firms''; (4) Luxor commented that there is no evidence to prove that the proposal will cure the problem it is intended to solve; (5) Massachusetts wrote that the annual calculation is predictable and may provide an incentive for firms to comply only enough to remain just below the triggering thresholds; (6) Cambridge predicted that member firms without significant retained earnings would be given exceptions to the Restricted Deposit Requirement; (7) Network 1 wrote ''[t]here will always be 'bad' brokers''; and (8) ASA commented that certain aspects of the proposal ''do not go far enough to remove the most egregious actors from our industry'' and would ''marginally increase the financial obligations of bad actor firms and allow [them] to continue their abuse of Main Street investors.''

The primary goal of the proposed rule change is to incentivize members with a significant history of misconduct relative to their peers to change behavior, and FINRA believes that the proposed rule change is reasonably designed to achieve that goal. The way the proposal identifies the affected firms is consistent with recent academic studies that analyzed correlations between disclosure data and risks to investors. The proposed rule change creates substantial, ongoing incentives for the firms that present the highest levels of risk to change behavior, and gives FINRA an important new tool to respond to those firms that continue to present outlier-level risks to investors. FINRA also believes that the most effective measure to incentivize such

[77] *See* proposed Rule 4111(i)(15)(A) (including as factors, inter alia, the ''nature of the firm's operations and activities'' and ''the number of offices and registered persons,'' and requiring that the Department determine a maximum Restricted Deposit Requirement that ''would not significantly undermine the continued financial stability and operational capability of the firm as an ongoing enterprise over the next 12 months'').

[78] Brooklight, Dempsey, Joseph Stone, Westpark.

[79] Dempsey, Joseph Stone.

[80] Brooklight, Dempsey, Joseph Stone.

[81] *See* Securities Exchange Act Release No. 88600 (April 8, 2020), 85 FR 20745 (April 14, 2020) (Notice of Filing of File No. SR–FINRA–2020–011).

[82] *See* Rule 3170 (Tape Recording of Registered Persons by Certain Firms). The Taping Rule provides, in general, that a firm is a ''taping firm'' when specified percentages of its registered persons have been associated with one or more ''disciplined firms'' in a registered capacity within the last three years.

[83] *See* Securities Exchange Act Release No. 17371 (December 12, 1980), 45 FR 83707 (December 19, 1980) (Order Approving File No. SR–NASD–78–3) (explaining that disparate treatment of differently situated parties is not necessarily either fair or unfair).

[84] ASA, Dempsey, Joseph Stone, Luxor, PIABA, Rockfleet, Worden.

[85] ASA, Better Markets.

[86] Cetera, Dempsey, Luxor.

firms to change behavior is a financial restriction—including the mere potential for a financial restriction.

Several commenters state that the proposal's impacts are too broad to address the risks posed. For example, Brooklight expressed that instead of impacting just a ''few bad actors,'' the proposal imposes increased regulatory burdens on ''every single member'' and could ''sweep in wholly innocent firms.'' HLBS commented that the proposed rule would impose punishment based only on the mere suspicion of misconduct. Rockfleet commented that the burdens would be unwarranted, because unpaid arbitration awards are ''not a widespread industry issue,'' and the proposal would unfairly capture firms that only employ a single individual with numerous disclosure events. Sichenzia commented that reducing unpaid arbitration awards is better achieved through less onerous means. FSI expressed concern that the proposal does not provide adequate safeguards to protect against misidentification.

FINRA believes, however, that the proposed rule change is reasonably designed to impact a relatively small number of firms posing outlier-level risks. The proposed Rule 4111 ''funnel'' process has numerous safeguards designed to protect against misidentification. Furthermore, although the proposal would have ancillary benefits for addressing unpaid arbitration awards, the proposal's primary purpose is to create incentives for members that pose outlier-level risks to change behavior.

Luxor commented that the proposal is inconsistent with the usual ''causal relationship inherent in any regulatory schema'' where misconduct precedes the sanctions imposed. Proposed Rule 4111, however, is similar to other kinds of rules and regulations that impose requirements and restrictions based on a firm's circumstances. For example, FINRA's membership rules permit FINRA to impose restrictions on new member applicants that are reasonably designed to address specific concerns, including—besides disciplinary concerns—financial, operational, supervisory, investor protection, or other regulatory concerns.[87] As another example, Exchange Act Rule 15c3–1,[88] the Net Capital Rule, imposes different minimum net capital requirements based on the types of securities business the broker-dealer conducts. Moreover, the obligations that FINRA may impose pursuant to Rule 4111 are not ''sanctions'' for violations; rather, they are obligations that relate directly to firm profiles that pose substantially more risk to investors than the profiles of the vast majority of other member firms of similar sizes.

Some commenters opposed the proposal on the ground that it is unnecessary. For example, Rockfleet commented that FINRA's membership program and examinations should be sufficient to deal with firms that have a poor supervisory structure and compliance culture. Likewise, Network 1 wrote that FINRA's enforcement program is a practical solution for addressing ''bad brokers.'' As explained above, however, while FINRA has a number of tools for identifying and addressing a range of misconduct by individuals and firms, and has strengthened these protections for investors and the markets, persistent compliance issues continue to arise in some member firms. Proposed Rule 4111 reflects FINRA's belief that more can be done to protect investors from firms with a significant history of misconduct.

Notwithstanding that FINRA has generally retained the proposal as it was originally proposed, FINRA appreciates the concerns raised by the commenters about the potential impacts and effectiveness of proposed Rule 4111. If approved, FINRA plans to review proposed Rule 4111 after gaining sufficient experience under the rule, at which time it will assess the rule's ongoing effectiveness and efficiency.

3. Concerns That the Proposal Gives FINRA Too Much Discretion, and Requests for Increased Transparency

Several commenters contended that, in numerous respects, the proposal gives FINRA too much discretion.[89] Commenters pointed to how the proposal gives the Department discretion to decide: (1) In the initial Department evaluation stage, which firms require further review; (2) the maximum and actual Restricted Deposit Requirement; and (3) the types of conditions or restrictions that may be imposed.[90] Some commenters further requested that the proposal provide more transparency on how FINRA would exercise its discretion. For example, Sichenzia suggested which kinds of disclosure events FINRA should eliminate from consideration during the initial Department evaluation, and some commenters requested that FINRA clarify how the Department would calculate a Restricted Deposit Requirement[91] and what kinds of conditions or restrictions could be imposed.[92] Some commenters recommended specific conditions and restrictions that FINRA should impose.[93]

FINRA believes that the proposal contains numerous steps that are objective and do not involve the use of discretion or that limit or focus FINRA's discretion. FINRA notes that the annual calculation—the first and most significant step that identifies member firms that are subject to the proposed rule—does not involve the use of discretion. The annual calculation uses objective, transparent criteria to identify outlier firms with the most significant history of misconduct relative to their peers (based on a review of the criteria as if it existed today, the number of member firms would be between 45–80 firms). Following the annual calculation, the Department would conduct an evaluation to review whether it has information that a member firm's calculation included disclosure events or conditions that should not have been included because they are not consistent with the purpose of the Preliminary Criteria for Identification and are not reflective of a firm posing a high degree of risk, whether the member has already addressed the concerns signaled by the disclosure events or conditions, or whether the member firm has altered its business operations such that the calculation no longer reflects the member firm's current risk profile. During the Consultation, the Department would evaluate whether the member firm has demonstrated that the calculation included disclosure events that should not have been included (because they are duplicative or not sales-practice related). When the Department considers whether a member firm should be subject to the maximum Restricted Deposit Requirement, it will evaluate whether the maximum amount would impose an undue financial hardship and whether a lesser amount, or conditions and restrictions, would satisfy the objectives of the rule and be consistent with the protection of investors and the public interest. The ability to request a Hearing Officer's review also would protect against overreaching.

[87] *See* Rule 1014(c)(2) (describing granting of applications for new membership subject to restrictions).

[88] 17 CFR 240.15c3–1.

[89] CAI, Cambridge, FSI, Sichenzia, Westpark.

[90] CAI, Cambridge, FSI, Rockfleet, Sichenzia, Westpark, Whitehall.

[91] CAI, Westpark, Whitehall.

[92] FSI, Massachusetts, NASAA, PIRC, St. John's SOL.

[93] Massachusetts, MIRC, NASAA, St. John's SOL.

To ensure that the member firms identified as Restricted Firms are of the type motivating this proposal and incentivize Restricted Firms to reduce the risks posed to investors, however, the Department will need some degree of flexibility to identify, react and respond to different sources of risk. For this reason, the revised proposal retains the ability of the Department to make internal assessments during the evaluation and Consultation, including ones concerning the amount of the Restricted Deposit Requirement and the conditions and restrictions that may be imposed, to appropriately address the concerns indicated by the Preliminary Criteria for Identification.

Nevertheless, FINRA agrees with commenters' request for additional clarity regarding the conditions and restrictions that could be imposed under the proposed rule.[94] For this reason, the revised proposal provides a non-exhaustive list of conditions and restrictions that could be imposed on Restricted Firms. Moreover, the proposed rule's descriptions of the Department's tasks and discretion are broad enough to allow FINRA to provide further guidance as it gains experience implementing the rule. For example, FINRA could provide additional guidance if it learns of categories of disclosure events that could be described as not consistent with the purpose of the Preliminary Criteria for Identification or not reflective of a firm posing a high degree of risk. FINRA also could provide further guidance on the kinds of conditions and restrictions that might be warranted in different contexts.

4. Comments Concerning the Preliminary Criteria for Identification

Numerous commenters suggested alternatives to several aspects of the Preliminary Criteria for Identification. Some suggested narrower criteria, including, for example, requests to: (1) Exclude criminal events in which the registered person pled nolo contendere; [95] (2) exclude or narrow criteria based on final regulatory actions; [96] (3) remove or narrow criteria based on pending events or unadjudicated events; [97] (4) remove or modify the criteria based on terminations or internal reviews; [98] (5) remove or substantially narrow the Expelled Firm Association Metric; [99] (6) increase the $15,000 threshold for settlements [100] and establish a minimum threshold for awards and judgments; [101] (7) decrease the lookback period; [102] (8) distinguish between events by recidivist and non-recidivist brokers; [103] (9) exclude all matters that are not sales-practice or investment-related [104] or that do not involve customer harm; [105] (10) address or remove ''nuisance arbitrations . . . settled without admission of guilt'' and ''disclosure events . . . filed by a compensated non-attorney representative''; [106] (11) narrow the term ''Registered Persons In-Scope'' to exclude persons who were registered with a member firm for only one day and include only those who have been employed with a member firm for at least 180 days; [107] (12) reconsider the inclusion in the criteria of settlements of arbitrations and regulatory actions,[108] disclosure events against persons who were named due to their position within a chain of supervision,[109] and ''allegation-driven'' disclosures; [110] and (13) account for widespread product or market collapse that could result in a high number of new disclosure events.[111]

Some commenters suggested broader criteria, including requests to: (1) Lower the dollar threshold for settlements; [112] (2) increase the lookback period; [113] (3) include financial disclosures like judgments, liens, bankruptcies and compromises; [114] (4) include non-investment related civil matters that involve dishonesty, deceit, or reckless or intentional wrongdoing; [115] (5) include internal reviews by other member firms; [116] (6) include a category based on specific products sold by the member firm; [117] and (7) include expunged Registered Person Adjudicated Events.[118]

Two commenters criticized or questioned how the metrics thresholds were based on firm size.[119]

In response to the comments about the proposed criteria's underlying categories and metrics, FINRA made two modifications to the proposal in *Regulatory Notice* 19–17. First, as explained above, the revised proposal uses a narrower definition of Registered Persons Associated with Previously Expelled Firms. Instead of an unlimited lookback over a registered person's entire career and no limitations based on the duration of the person's registration with the expelled firm as originally proposed in *Regulatory Notice* 19–17, the revised proposal would include only those registered persons who were registered with a previously expelled firm for at least one year and within the five years prior to the date the Preliminary Criteria for Identification are calculated. Persons' previous registrations with expelled firms (*i.e.,* beyond the five-year lookback) would not be counted in this category or towards an employing member firm's Expelled Firm Association Metric. Moreover, FINRA believes using a five-year lookback would be consistent with the lookback periods for the other metrics.[120]

Second, FINRA believes that the comments about the termination and internal review events demonstrated a need for clarification of the relevant metric. The revised proposal would make clear that termination and internal review disclosures concerning a person that a member firm terminated would not impact that member firm's own Registered Person Termination and Internal Review Metric; rather, those disclosures would only impact the metrics of member firms that subsequently register the terminated individual.

Otherwise, FINRA has decided to retain the rest of the Preliminary Criteria for Identification as originally proposed in *Regulatory Notice* 19–17. Many of the commenters' other proposed alternative definitions and criteria comments concern issues that FINRA already considered and addressed in the economic assessment in *Regulatory Notice* 19–17, and the comments have not persuaded FINRA that any changes would be more efficient or effective at addressing the potential for future

[94] *See, e.g.,* FSI, NASAA, PIRC.

[95] Westpark.

[96] Moss & Gilmore, Westpark.

[97] AdvisorLaw, Cambridge, Cetera, HLBS, Joseph Stone, Luxor, Moss & Gilmore, Westpark, Worden.

[98] Cambridge, Cetera, Westpark. Two of these commenters cautioned that including termination and internal review events could discourage firms from conducting internal reviews and filing appropriate termination disclosures on the Uniform Registration Forms, thereby reducing internal compliance procedures and potentially leading to underreporting of such events. Cetera, Westpark.

[99] Cambridge, Cetera, Joseph Stone, Luxor, Network 1, Sichenzia, Westpark.

[100] Cambridge, Joseph Stone, Luxor.

[101] Cambridge.

[102] Westpark.

[103] Sichenzia.

[104] Cambridge.

[105] Westpark.

[106] Luxor, Moss & Gilmore, Sichenzia.

[107] Westpark.

[108] HLBS, Moss & Gilmore, Westpark.

[109] Cambridge, Westpark.

[110] Worden.

[111] Cambridge.

[112] Better Markets.

[113] Better Markets.

[114] Massachusetts, NASAA.

[115] Massachusetts.

[116] Massachusetts.

[117] MIRC, PIABA.

[118] NASAA.

[119] Rockfleet, Worden.

[120] FINRA analyzed whether the revised Expelled Firm Association Metric still preserves its usefulness, and FINRA determined that it does, as explained in the Economic Impact Assessment.

customer harm presented. As FINRA explained in *Regulatory Notice* 19–17, the primary benefit of the proposed rule change would be to reduce the risk and associated costs of possible future customer harm by member firms that meet the proposed criteria, by applying additional restrictions on firms identified as Restricted Firms and by the increased scrutiny that will likely result by these firms on their brokers. In developing this proposal, one of the guiding principles was to provide transparency regarding the proposal's application, so that firms could largely identify with available data the specific set of disclosure events that would count towards the proposed criteria and whether the firm had the potential to be designated as a Restricted Firm. This is why—unlike many of the alternatives suggested by commenters—FINRA's proposal is based on events disclosed on the Uniform Registration Forms, which are generally available to firms and FINRA.

Several commenters expressed concern over how the Preliminary Criteria for Identification relies on data in the Uniform Registration Forms.[121] Several commenters contended that there are underlying problems with the information disclosed through the Uniform Registration Forms, stemming primarily from the allegation-based disclosures that must be made and frivolous arbitrations.[122] One commenter pointed to the number of expungements as evidence of the unreliability of the disclosure data.[123] NASAA, PIABA, and some law school clinics raised a concern from a different perspective, writing that expungements are granted too frequently and will cause the annual calculation of the Preliminary Criteria for Identification to not identify all firms that pose the highest risks.[124] Relatedly, several commenters suggested that the proposed Preliminary Criteria for Identification highlights problems with expungements, including that the proposal will incentivize even more expungement requests,[125] that FINRA should simultaneously pursue meaningful expungement reform,[126] or that FINRA should make it easier to expunge certain customer dispute information because Uniform Registration Form disclosures would now carry greater weight.[127] Some commenters predicted that the proposal will create perverse incentives to avoid making required disclosures on the Uniform Registration Forms.[128]

FINRA believes, however, that the data reported on the Uniform Registration Forms is reliable enough on which to base proposed Rule 4111. FINRA rules require firms and individuals to make accurate disclosures, and they could be subject to disciplinary action and possible disqualification if they fail to do so. Regulators are the source of disclosures on Form U6. FINRA's Department of Credentialing, Registration, Education and Disclosure conducts a public records review to verify the completeness and accuracy of criminal disclosure reporting. And although some commenters take issue with some of the specific events that must be disclosed on the Uniform Registration Forms, the SEC has taken the position that ''essentially all of the information that is reportable on the Form U4 is material.'' [129]

FINRA recognizes that the number of expungement requests may increase as a result of this proposal. However, the existing regulatory framework and FINRA rules are designed to ensure that expungements are granted only after a neutral adjudicator (arbitrator or judge) concludes that expungement is appropriate. Furthermore, OCE has tested the proposed thresholds in several ways using the existing Central Registration Depository (''CRD'') data, including comparing the firms captured by the proposed thresholds to the firms that have recently been expelled, that have unpaid arbitration awards, that Department staff has identified as high risk for sales practice and fraud based on the Department's own risk-based analysis, and that subsequently had additional disclosures after identification. Moreover, FINRA is actively engaged in efforts to address concerns with the current system of arbitration-based expungement of customer allegations from brokers' records.[130] FINRA's planned review of proposed Rule 4111 would necessarily account for any future amendments to the expungement process and any associated impact on the underlying data in CRD. Accordingly, FINRA does not believe that the proposal would directly result in inappropriate expungements being granted or appropriate expungements being not granted, or that it would undermine the quality of the underlying CRD information used for the proposed metrics.

5. Annual Calculation of the Preliminary Criteria for Identification

Massachusetts contends that calculations of the Preliminary Criteria for Identification should occur more than annually. FINRA appreciates this suggestion, but believes that it should gain experience with an annual requirement before considering whether to conduct more frequent reviews.

SIFMA requested that the proposal provide more transparency around the variables for the annual calculation of the Preliminary Criteria for Identification, so that firms can have the same ability as FINRA to calculate whether they meet the thresholds. For example, SIFMA explained that firms will need specific information about the Evaluation Date to make the calculations on their own.

FINRA agrees that additional clarity should be provided regarding the timing of the calculation. Proposed Rule 4111 is intended to be transparent enough so that member firms can understand whether they are at risk of being subject to additional obligations, and member firms will need to know the exact Evaluation Date to do their own calculations. FINRA would announce in a *Regulatory Notice* the first Evaluation Date no less than 120 days before the first Evaluation Date. FINRA also would announce that subsequent Evaluation

[121] AdvisorLaw, Cambridge, Moss & Gilmore, Worden.

[122] AdvisorLaw, Cambridge, Moss & Gilmore, Worden.

[123] AdvisorLaw.

[124] MIRC, NASAA, PIABA, PIRC.

[125] MIRC, NASAA, PIABA, PIRC.

[126] NASAA, PIABA.

[127] Cambridge.

[128] Cetera, PIRC, St. John's SOL.

[129] *Joseph S. Amundsen,* Exchange Act Release No. 69406, 2013 SEC LEXIS 1148, at *41 (Apr. 18, 2013), *aff'd,* 575 F. App'x 1 (D.C. Cir. 2014).

[130] FINRA recently filed a proposed rule change that would amend the Codes of Arbitration Procedure for Customer and Industry Disputes (''Codes'') to modify the current process relating to requests to expunge customer dispute information. The proposed rule change would amend the Codes to: (1) Impose requirements on expungement requests filed either during an investment-related, customer-initiated arbitration or separate from a customer-initiated arbitration (''straight-in requests''); (2) establish a roster of arbitrators with enhanced training and experience from which a three-person panel would be randomly selected to decide straight-in requests; (3) establish procedural requirements for expungement hearings; and (4) codify and update the best practices of the Notice to Arbitrators and Parties on Expanded Expungement Guidance that arbitrators and parties must follow. *See* Securities Exchange Act Release No. 90000 (September 25, 2020), 85 FR 62142 (October 1, 2020) (Notice of Filing of File No. SR–FINRA–2020–030); Notice to Arbitrators and Parties on Expanded Expungement Guidance, available at *https://www.finra.org/arbitration-andmediation/notice-arbitrators-and-parties-expanded-expungement-guidance*). In addition, FINRA recently amended the Codes to apply minimum fees to requests to expunge customer dispute information. *See* Securities Exchange Act Release No. 88945 (May 26, 2020), 85 FR 33212 (June 1, 2020) (Order Approving Filing of File No. SR–FINRA–2020–005); *Regulatory Notice* 20–25 (July 2020).

Dates would be on the same month and day each year, except when that date falls on a Saturday, Sunday, or federal holiday, in which case the Evaluation Date would be on the next business day.

Some commenters requested that FINRA provide member firms with assistance in determining if they meet the Preliminary Criteria for Identification. For example, CAI requested clarification on whether FINRA would provide advance notice to firms that meet or come close to meeting the Preliminary Criteria for Identification. Cambridge wrote that FINRA should notify firms in advance that they meet the criteria and publish a list of expelled firms. SIFMA requested that FINRA provide an electronic worksheet, available year round.

FINRA does not currently plan to provide member firms with advance notice about whether they would meet, or are close to meeting, the Preliminary Criteria for Identification, because the calculation under the proposal would occur annually, not on a rolling basis, and calculating the events included in the Preliminary Criteria for Identification based on an earlier date may lead to different results. Moreover, the proposed rule is designed to be transparent enough to allow member firms to perform their own calculations. FINRA agrees, however, that additional guidance and resources could facilitate member firms' independent calculations, and FINRA will explore ways to provide helpful resources. For example, this could include mapping the Disclosure Event and Expelled Firm Association Categories to the relevant disclosure questions on the Uniform Registration Forms. It also could include making available, year round, a worksheet that member firms could populate with the number of Registered Persons In-Scope, the number of disclosure events in each category, and the number of Registered Persons Associated with Previously Expelled Firms to generate information about whether the member firm meets or is close to meeting the Preliminary Criteria for Identification.[131] FINRA also would consider making available to member firms a list of expelled firms, if that information is burdensome for member firms to obtain on their own.

[131] Such a year-round worksheet could be a tool for member firms to monitor their status in relation to the Preliminary Criteria for Identification, but not a determinate one. Whether a member firm will meet the criteria could only be definitively established on the annual Evaluation Date.

6. One-Time Staffing Reduction

Several comments addressed the proposal's one-time staffing reduction opportunity. PIRC expressed support for the one-time staffing reduction opportunity, commenting that it will have the benefit of lowering the number of representatives who have repeatedly harmed investors. Joseph Stone commented that member firms should have several opportunities to reduce staff, not just one. Westpark stated that the one-time opportunity should renew after three years. HLBS called the staffing reduction opportunity the proposal's ''most alarming and punitive measure,'' because member firms would ''conduct a mass termination not because of an independent business decision but because . . . failing to do so . . . would essentially result in financial ruin.''

FINRA has retained the one-time staffing reduction opportunity as originally proposed. The one-time staffing reduction opportunity is intended to provide another procedural protection for member firms, because it would give a firm that meets the Preliminary Criteria for Identification one opportunity to reduce staff so as to fall below the criteria's thresholds. It has been designed as only a single opportunity to deter member firms from resurrecting a high-risk business model after a staff reduction. Moreover, FINRA does not agree with HLBS's assertion that the proposed staffing reduction opportunity removes member firms' independence to make business decisions. FINRA believes that a member firm that meets the Preliminary Criteria for Identification, possibly inadvertently, in one year should have the choice of whether to exercise the staffing reduction option. Furthermore, a firm that chooses to exercise the staffing reduction option would have the independence to decide how to proceed going forward, with the knowledge that it has once met the Preliminary Criteria for Identification, that the preliminary criteria are fully transparent, and that it would not have another opportunity to reduce staff to avoid a review under Rule 4111.

Better Markets stated that the staffing reduction opportunity needs to better protect investors, by prohibiting other high-risk firms from hiring terminated persons, prohibiting any firms from hiring the terminated persons for one year, or requiring that staff reductions commence with brokers with the highest number of disclosure events or with frequent and severe violations. FINRA is already pursuing, however, a separate proposal that would require a member firm to request a materiality consultation with FINRA staff when a person who has one final criminal matter or two ''specified risk events'' seeks to become an owner, control person, principal or registered person of the member.[132] That related proposal would potentially impact persons terminated pursuant to the staffing reduction opportunity.

7. Consultation

Westpark commented that proposed Rule 4111 does not give firms enough time to prepare for the Consultation. Because the proposed rule sets tight deadlines for the Department's decision, FINRA agrees that the proposed deadlines for the Consultation would also be tight. For this reason, FINRA has revised proposed Rule 4111(d)(2) to require that the letter scheduling the Consultation provide at least seven days' notice of the Consultation date, and also give the member firm the opportunity to request a postponement of the Consultation for good cause shown. Postponements would not exceed 30 days unless the member firm establishes the reasons a longer postponement is necessary.

Other comments about the Consultation did not prompt FINRA to make revisions. For example, FSI commented that the Consultation should be an opportunity for FINRA to work collaboratively with the identified firm. FINRA believes the Consultation is already intended to give member firms an opportunity to meet with FINRA and demonstrate why the calculation of the Preliminary Criteria for Identification should not include certain events or provide a rationale as to why the firm should not be required to maintain the maximum Restricted Deposit Requirement. As such, FINRA does not believe further revisions are necessary.

Chiu and Luxor wrote that although proposed Rule 4111 would allow members during the Consultation to request a waiver of the maximum Restricted Deposit Requirement for financial hardship reasons, member firms will not do so because it would deter recruitment and cause brokers to leave. Allowing member firms to demonstrate undue financial hardship, however, is consistent with the intent of the Restricted Deposit Requirement that it not significantly undermine the member firm's continued financial stability and operational capability as an ongoing enterprise over the next 12 months. Moreover, FINRA anticipates

[132] *See* Securities Exchange Act Release No. 88600 (April 8, 2020), 85 FR 20745 (April 14, 2020) (Notice of Filing of File No. SR–FINRA–2020–011).

that member firms subject to the requirement will not be deterred from asserting that a Restricted Deposit Requirement would cause an undue financial hardship, given that such arguments could lead to a reduced Restricted Deposit Requirement or no deposit requirement at all. Moreover, the proposal would not make public any such assertions by a member firm.

In a comment related to the Consultation, FSI commented that firms should not shoulder the risk of misidentification, and that FINRA should have to demonstrate its reasons for continuing the review process for firms preliminarily identified as high risk. Proposed Rule 4111 only places burdens of proof on the small number of firms that meet the Preliminary Criteria for Identification and that the Department determines, after conducting its initial evaluation, warrants further review. Each of these firms would have the opportunity to overcome the presumption that it should be designated as a Restricted Firm and subject to the maximum Restricted Deposit Requirement. Under the proposed rule, the affected firms would initiate this process because they would be in the best position to provide the relevant information. For example, proposed Rule 4111(d)(1)(A) would provide that a member firm may overcome the presumption that it should be designated as a Restricted Firm by clearly demonstrating that the Department's calculation included events that should not have been included because, for example, they are duplicative, involving the same customer and the same matter, or are not sales practice related. The member firm, not Department staff, is in the best position to provide that kind of information about the disclosure data. Likewise, the member firm would be in the best position to demonstrate, pursuant to proposed Rule 4111(d)(1)(B), that it would face undue financial hardship if it were required to maintain the maximum Restricted Deposit Requirement.

8. Restricted Deposit Requirement

FINRA also received general comments concerning the proposed Restricted Deposit Requirement concept. Some commenters were generally opposed to the proposed requirement. Their reasons include: (1) A deposit requirement may trigger unintended consequences which result in harm to the investing public; [133] (2) a deposit requirement may lead to competitive disadvantages, because members without significant retained earnings may receive exceptions, while members with greater working capital would not; [134] (3) the only members likely to be able to satisfy a deposit requirement would be ones that do not anticipate being subject to the rule; [135] (4) a deposit requirement would ''result[ ] in cash flow problems, increased borrowing, and layoffs'' [136] and a ''devastating economic impact'' on the broker-dealer and its employees, customers, vendors, and counterparties; [137] (5) restricted funds could be better used for other purposes; [138] (6) there is little evidence why restricted deposits are necessary; [139] (7) requiring ''up front financing of uninsured claims, many of which are specious, would have negative net capital implications''; [140] (8) any assertion that unpaid arbitration awards is rampant and justifies the deposit requirement is false; [141] (9) a deposit requirement would put small firms out of business and result in less choice for investors; [142] and (10) many members do not have sufficient cash to hold as restricted deposits.[143]

Other commenters were generally supportive of the Restricted Deposit Requirement concept. PIRC said that Restricted Deposit Requirements should help deter misconduct and also help FINRA ''rein in Restricted Firms that shut down and reconstitute themselves in an attempt to avoid paying settlements and awards.'' SIFMA opined that the proposal ''appropriately embraces the 'front-end' approach'' to addressing unpaid awards by ''seeking to identify those small number of firms with an extensive history of misconduct and/or relevant disclosure events, and as appropriate, requiring [them] to set aside cash deposits or qualified securities that could be applied to . . . unpaid awards.''

FINRA's proposal continues to provide that the Department could impose a Restricted Deposit Requirement on Restricted Firms. FINRA believes that a financial requirement is the measure most likely to motivate Restricted Firms to change behavior. As such, the Restricted Deposit Requirement is an essential feature of the proposal to protect investors, with the possible secondary benefit of helping to address the issue of unpaid arbitration awards. Moreover, the proposal attempts to counteract firms' preemptively withdrawing capital by instructing the Department to consider several financial factors—not just net capital—when determining a Restricted Deposit Requirement. In addition, FINRA believes the implications of a Restricted Deposit Requirement on a member firm's net capital levels—that a member firm would have to deduct deposits in Restricted Deposit Accounts in determining the firm's net capital [144]—is one reason why the proposal would incentivize member firms to avoid becoming Restricted Firms, not a reason to abandon the Restricted Deposit Requirement concept. Finally, the proposal contemplates that the Restricted Deposit Requirement should correlate to the financial realities at the member firm, and allows the firm to attempt to demonstrate that it would impose undue financial burdens.[145]

9. Calculating a Restricted Deposit Requirement

FINRA received several comments about the Department's determination of a Restricted Deposit Requirement. CAI expressed support for some of the proposed factors that the Department would consider when calculating the Restricted Deposit Requirement. In addition, CAI endorsed the proposed limitation in proposed Rule 4111(i)(15) that the maximum Restricted Deposit Requirement be an amount that would not significantly undermine the continued financial stability and operational capability of the firm as an ongoing enterprise over the next 12 months.

Several commenters expressed concerns about the proposed factors that the Department would consider when calculating the Restricted Deposit Requirement. For example, Sichenzia called the factors ''arbitrary''; some commenters opposed the inclusion of, or requested modifications to, the

[133] Cambridge.

[134] Cambridge.

[135] Cambridge.

[136] Westpark.

[137] Rockfleet.

[138] Chiu.

[139] Brooklight.

[140] Moss & Gilmore.

[141] Moss & Gilmore.

[142] Chiu, IBN, Whitehall. Whitehall also wrote that the proposal entails ''FINRA . . . demanding funds for itself'' and ''using [members] as bank accounts to expand'' FINRA's activities. Nothing in the proposal, however, results in FINRA receiving any assets from firms. At all times, a Restricted Firm would continue to own the assets that it maintains in a Restricted Deposit Account.

[143] Whitehall.

[144] *See* proposed Rule 4111.01.

[145] Westpark commented that proposed Rule 4111 is inconsistent with Section 15A(b)(5) of the Exchange Act, which requires that FINRA's rules ''provide for the equitable allocation of reasonable dues, fees, and other charges among members.'' The proposed Restricted Deposit Requirement, however, is not a due, fee or charge. Assets that a member maintains in a Restricted Deposit Account would remain the member's assets; they would not be provided to, used by, or owned by FINRA.

''Covered Pending Arbitration Claims'' factor;[146] Network 1 commented that the Restricted Deposit Requirement should not consider ''bona fide nuisance claims brought in arbitration''; Cambridge objected to the ''gross revenues'' factor, on the grounds that that factor would not contemplate the firm's contractual obligations for which the revenues have already been allocated; and Moss & Gilmore objected to considering ''concerns raised during FINRA exams'' on the grounds that ''novice examiners . . . [often] conduct the front-line examinations.''[147]

Some commenters believed that the list of factors should be expanded. For example, two commenters requested that FINRA account for instances in which the firm has insurance coverage for arbitration claims.[148] MIRC commented that the Covered Pending Arbitration Claims factor should be expanded to include other kinds of pending claims that could lead to unpaid awards, not just ones limited to the arbitration setting. PIABA requested that the Restricted Deposit Requirement calculation also take into account the nature and extent of harm that the Restricted Firm has done in the past.

As explained above, FINRA has made several revisions to the factors that the Department would consider when determining a maximum Restricted Deposit Requirement. The ''annual revenues'' and ''net capital requirements'' factors proposed in *Regulatory Notice* 19–17 have been modified to ''revenues'' and ''net capital,'' and ''assets,'' ''expenses,'' and ''liabilities'' have been added as factors. In addition, FINRA has clarified that unpaid arbitration awards against a member firm's Associated Persons is one relevant factor. FINRA believes this modified and expanded list of factors would lead to a more complete consideration of the firm's financial situation.

FINRA has retained the other proposed factors, however, because they appropriately and accurately describe the factors, financial and otherwise, that would be most relevant to the Department when calculating a Restricted Deposit Requirement. This includes the Covered Pending Arbitration Claims factor. Because one purpose of the Restricted Deposit Requirement is to preserve some of a Restricted Firm's assets for potential payment of arbitration awards, FINRA believes that purpose is served by allowing the Department to consider Covered Pending Arbitration Claims when determining a Restricted Deposit Requirement. At the same time, the revised proposed rule also adds as a factor the member's ''insurance coverage for customer arbitration awards or settlements.'' FINRA believes that if Restricted Firms were able to procure errors and omissions insurance policies or other kinds of insurance coverage for some or all of the kinds of claims that customers typically bring in arbitrations, at meaningful coverage amounts, that could warrant a reduced Restricted Deposit Requirement and would be behavior to encourage.

Two commenters contended that because potential liabilities relating to pending arbitrations must be accrued on financial statements, a Restricted Deposit Requirement that is based in part on Covered Pending Arbitration Claims (which would be a non-allowable asset) would ''double[ ] the net capital impact.''[149] While there would not usually be a double impact—accruals of contingent liabilities based on pending arbitrations usually reflect only a small percentage of the potential liability—a member firm's net capital level could be impacted by a Restricted Deposit Requirement based in part on Covered Pending Arbitration Claims and a member firm's accruals of potential liabilities stemming from the same pending arbitration claims. For this reason, the Department's consideration of Covered Pending Arbitration Claims could take into account whether any liability accruals for those same claims warrant a reduction in the Restricted Deposit Requirement. It should be noted, however, that the purposes of accruing a liability on a financial statement are different from the purposes of the proposed Rule 4111 requirement to deposit money in a Restricted Firm's segregated, restricted account.

In addition to comments about the specific factors that the Department would consider, some commenters requested that the proposal describe with more specificity how the Restricted Deposit Requirement would be calculated or establish caps. CAI, for example, requested that FINRA develop specific limitations such as caps and a formula that focuses on the correlation between revenues that may give rise to unpaid arbitration awards (*e.g.,* penny stock sales) and unpaid arbitration award amounts. FSI suggested that FINRA use published guidelines to provide transparency. Westpark suggested that the proposal should cap the Restricted Deposit Requirement at a specified percentage of required net capital amounts or a percentage of average net income over a three-year lookback period. Whitehall asked whether FINRA would have a formula for calculating the Restricted Deposit Requirement. MIRC suggested that FINRA should impose Restricted Deposit Requirements that are sufficient to meet all unpaid awards and pending claims related to products and product types.

FINRA has not proposed a uniform formulaic approach for calculating the Restricted Deposit Requirement because of the range of relevant factors and differences in member firms' business models, operations, and financial conditions. In addition, although formulas do provide objective, transparent methodologies, here they would allow member firms the opportunity to manipulate their revenue numbers during the calculation periods. For these reasons, FINRA has retained the factor-based, principles-based approach to determining a Restricted Deposit Amount.

10. Impact on Unpaid Arbitration Awards

PIABA contended that the proposal will not solve the issue of unpaid arbitration awards, because there is no indication that the Restricted Deposit Requirements will be sufficient to cover anticipated arbitration awards. Relatedly, several commenters requested that the proposal also provide more clarity on how the Restricted Deposit Requirement could be used to pay investor claims.[150]

[146] Moss & Gilmore, Network 1, Sichenzia, Westpark.

[147] Moss & Gilmore.

[148] Network 1, Sichenzia.

[149] Network 1, Rockfleet.

[150] MIRC, PIABA, PIRC.

With respect to the relationship between proposed Rule 4111 and unpaid arbitration awards, FINRA notes that FINRA rules currently prohibit member firms or registered representatives who do not pay arbitration awards in a timely manner from continuing to engage in the securities business under FINRA's jurisdiction.[151] As to proposed Rule 4111, it was designed to address a broader range of investor protection concerns posed by firms and individuals with a significant history of misconduct, including but not limited to unpaid arbitration awards. The Rule would apply to firms who, based on statistical analysis of their prior disclosure events, are substantially more likely than their peers to subsequently have a range of additional events indicating various types of harm or potential harm to investors.

Nevertheless, FINRA believes proposed Rule 4111 may have important ancillary effects in addressing unpaid customer arbitration awards. In particular, the Rule may deter behavior that could otherwise result in unpaid arbitration awards, by incentivizing firms to reduce their risk profile and violative conduct in order to avoid being deemed a Restricted Firm and becoming subject to the Restricted Deposit Requirement (or other conditions or restrictions). In addition, firms may be incentivized to obtain insurance coverage for potential arbitration awards, because such coverage would be taken into account in determining any Restricted Deposit Requirement. Moreover, and as explained above, the proposed rule includes several presumptions, applicable to the Department's assessment of an application by a firm previously designated as a Restricted Firm for a withdrawal from a Restricted Deposit, that would further incentivize the payment of arbitration awards.

FINRA has made several revisions to proposed Rule 4111(f) to make more clear the process that would guide the Department's evaluation of a request for a withdrawal from a Restricted Deposit Account. As explained above, these include several presumptions of approval or denial that set forth how Covered Pending Arbitration Claims or unpaid arbitration awards would impact the Department's evaluation. The presumptions of denial that would apply when a Restricted Firm or previously designated Restricted Firm applies for a withdrawal from a Restricted Deposit would still apply when the firm seeks to use the funds to satisfy unpaid arbitration awards; unless the presumption of denial can be overcome, those firms would generally need to satisfy unpaid arbitration awards using funds other than those in a Restricted Deposit Account.[152] There would be a separate presumption that a request by a former member firm previously designated as a Restricted Firm to access its Restricted Deposit would be approved when it commits in the manner specified by the Department to use the amount it seeks to withdraw from its Restricted Deposit to pay the former member's specified unpaid arbitration awards.

PIABA also raised the concern that thinly capitalized firms would have smaller Restricted Deposit Requirements. A member's thin capitalization at the time of the Consultation, however, would be only one factor of many that the Department would consider when determining a Restricted Deposit Requirement, and would not necessarily result in a lower requirement.

11. Custodians of the Restricted Deposit Account

Some commenters expressed concern about how proposed Rule 4111 would require the Restricted Deposit Account to be maintained with a bank or clearing firm. Rockfleet predicted that it will be unlikely that banks or clearing firms will create new policies and procedures for the small amount of Restricted Deposit Accounts that would result from the proposal. SIFMA commented that a number of clearing firms believe it would be problematic to custody a Restricted Deposit Account ''given the clearing firm's unique role in the relationship between an introducing broker and its clients,'' and how the proposed rule would impose additional duties and responsibilities that are not now part of clearing firms' systems and procedures. SIFMA also stated that custody by a clearing firm of the Restricted Deposit Requirement likely would not provide FINRA with the level of transparency that FINRA would want.

The revised proposal retains the option for Restricted Firms to establish Restricted Deposit Accounts with clearing firms. FINRA believes that member firms have an existing relationship with their clearing firms and should be permitted to establish the Restricted Deposit Account with them if the parties choose. Nothing in the proposal requires clearing firms to establish Restricted Deposit Accounts. Where a clearing firm is unwilling or unable to establish these accounts, the proposal would permit Restricted Firms to establish such accounts at banks.

SIFMA also commented that the proposal should be revised to expressly allow trust companies to maintain the accounts. FINRA believes that the original proposal includes many trust companies and so gives members sufficient options and flexibility.

12. Comments Concerning Proposed Expedited Proceedings

As originally proposed in *Regulatory Notice* 19–17, proposed Rule 9561(a) would have provided that any of the Rule 4111 Requirements imposed in a notice issued under proposed Rule 9561(a) would be immediately effective; that, in general, a request for a hearing would not stay those requirements; and that, if a member firm requests a hearing of a Department determination that imposes a Restricted Deposit Requirement for the first time, the member firm would be required to deposit, while the expedited proceeding was pending, the lesser of either 50% of its Restricted Deposit Requirement or 25% of its average excess net capital during the prior calendar year. Westpark commented that the expedited proceedings would not be meaningful because obligations would not be stayed. Luxor commented that the requirement to deposit a percentage of the Restricted Deposit Requirement would be ''devastating.''

[151] *See* FINRA Rule 9554. Under FINRA rules, unless a respondent has specified defenses to non-payment, the respondent must pay a monetary award within 30 days of receipt. *See* FINRA Rule 12904(j). In addition, firms with unpaid awards cannot re-register with FINRA and individuals cannot register as representatives of any member firm, without paying or discharging the outstanding award.

[152] *See* proposed Rule 4111(f)(1) and (f)(3)(B)(ii)(a).

In general, FINRA has retained the no-stay provisions as originally proposed. FINRA believes that the proposed no-stay provisions are a fundamental part of how the proposed rules would protect investors. Requiring Restricted Firms to comply with obligations imposed during the short pendency of an expedited proceeding would afford more immediate protections to investors from firms that pose outlier-level risks. Moreover, requiring immediate compliance with the Department's decision would be similar to other situations in which firms and individuals posing substantial risks must abide by FINRA decisions before underlying proceedings are resolved, such as when disciplinary respondents must abide by temporary cease and desist orders before an underlying disciplinary proceeding is complete or comply with FINRA-imposed bars while an SEC appeal is pending. Nonetheless, FINRA believes that one aspect of the proposed no-stay provisions could be less burdensome without compromising its intended purpose. Accordingly, FINRA has revised the proposed rules to lower the proposed partial-deposit requirement to the lesser of 25% of the Restricted Deposit Requirement or 25% of the firm's average excess net capital during the prior calendar year.

Cetera commented that the hearings should be conducted by a Hearing Panel that includes two industry members and one Hearing Officer, because Hearing Officers are viewed as ''not as objective.'' FINRA has retained, however, the proposal to have Hearing Officers preside over the new expedited proceedings. Hearing Officers preside over several kinds of proceedings.[153] And here, FINRA believes the need for swift proceedings as a result of the proposed no-stay provisions and to protect investors works in favor of the efficiency of Hearing Officer-only proceedings. Moreover, FINRA believes there are additional protections for the firms in the proposal, given that the Hearing Officer's authority will be circumscribed and that the NAC's Review Subcommittee will have the right to call the proceeding for review.

Cetera commented that the proposed rule would require hearings to be held in expedited proceedings in an unreasonably short time after the firm receives notice of its Restricted Firm status. FINRA believes, however, that the proposed rule offers reasonable time limits and an opportunity to seek extensions. Under proposed Rules 9561(a)(5) and 9559(f)(5), a member would be required to request a hearing within seven days after service of a notice of a determination that a firm is a Restricted Firm, and a hearing would be required to be held within 30 days after the member files that hearing request. In addition, under an existing provision in Rule 9559, the Hearing Officer could extend the time limits for holding the hearing for good cause shown or with the consent of all the parties.

PIABA commented that under proposed Rule 9561(b), which would establish an expedited proceeding to address a member firm's failure to comply with any requirements imposed pursuant to proposed Rule 4111, FINRA should be required to immediately suspend a non-compliant firm and should not have the discretion not to act. Although FINRA expects that non-compliant Restricted Firms would be a high priority for the Department of Enforcement, the revised proposal retains FINRA's prosecutorial discretion to ensure that FINRA can use its best judgments about how to deploy its limited resources.

Rockfleet commented that the proposed Rule 9561(b) expedited proceeding is counterintuitive, because canceling a Restricted Firm's membership would result in FINRA losing any control over the firm. FINRA respectfully disagrees and believes that proposed Rule 4111 must provide a tool for FINRA to compel the immediate compliance with obligations that have been imposed pursuant to the rule.

12. Procedural Protections

Several commenters contended that the proposal is an attempt to impose the equivalent of sanctions while avoiding the fair-process requirements that would be present in a disciplinary proceeding, and to ban persons who are not statutorily disqualified.[154] The proposed Rule 4111 process, however, is neither a disciplinary nor an eligibility proceeding, and the obligations that could be imposed pursuant to proposed Rule 4111 would not be sanctions imposed for violations. Furthermore, FINRA believes the proposal gives affected member firms substantial procedural protections. These include providing notice that a member has met the Preliminary Criteria for Identification and of the maximum Restricted Deposit Requirement; a one-time staffing reduction opportunity for firms that meet the Preliminary Criteria for Identification for the first time; a Consultation, which will allow affected firms to attempt to show why they should not be deemed Restricted Firms or be subject to the maximum Restricted Deposit Requirement; and the right to seek an expedited hearing before a Hearing Officer.[155] These procedural protections are in addition to the Preliminary Criteria for Identification, which would be fully transparent and enable firms to monitor whether they are at risk of meeting the threshold criteria.

Moreover, the proposal is neither intended nor designed to expel member firms and persons that are not statutorily disqualified. In this regard, FINRA notes that the rule text contains express language that the Department determine a maximum Restricted Deposit Requirement that ''would not significantly undermine the continued financial stability and operational capability of the firm as an ongoing enterprise over the next 12 months,'' and also contemplates situations in which Restricted Firms remain member firms for years. Furthermore, persons terminated pursuant to the Rule 4111 staffing reduction opportunity would be permitted to seek employment with any other member firm and allowed to apply to re-associate with the Restricted Firm after one year.[156]

13. Unintended Consequences

Rockfleet expressed concern that clearing firms will terminate clearing agreements for firms deemed to be Restricted Firms, and that firms using tri-party clearing agreements could be impacted through no fault of their own. CAI raised a concern that being deemed as a Restricted Firm could have ramifications for firms that are parties to selling agreements. FINRA appreciates that proposed Rule 4111 may have potential unintended consequences, and plans to examine issues like those when FINRA reviews proposed Rule 4111 after gaining sufficient experience under the rule.

14. Public Disclosure Issues

Several commenters addressed whether there should be public disclosure of a firm's status as a

[153] *See* FINRA Rule 9559(d) (providing that Hearing Officers preside over, and act as the sole adjudicator for, proceedings initiated under Rules 9553 (failures to pay FINRA dues, fees and other charges), 9554 (failures to comply with arbitration awards or related settlements or orders of restitution or settlements providing for restitution), and 9556(h) (subsequent proceedings for failures to comply with temporary or permanent cease and desist orders)).

[154] Brooklight, Luxor, Network 1, Rockfleet, Westpark.

[155] The right to have a Hearing Officer's decision reviewed by the SEC would be governed by Section 19 of the Exchange Act.

[156] Some commenters (Network 1, Westpark) asserted that the proposed rule change would be unconstitutional, for a variety of reasons. FINRA, however, is not a state actor.

Restricted Firm. Some opposed any disclosure at all, warning that disclosure could adversely impact the affected firms, and would make it more likely the firm would fail.[157] Several commenters, particularly regulators and public advocacy groups, argue that FINRA should disclose the names of Restricted Firms to the public or, at least, to other regulators or clearing firms.[158]

FINRA believes the aim of the proposal is to address the risks posed by Restricted Firms by imposing appropriate restrictions on them and, at the same time, providing them with opportunities and incentives to remedy the underlying concerns (*e.g.,* the one-time staff reduction, the opportunity to roll off the Restricted Firms list). Because requiring FINRA to publicly disclose a firm's Restricted Firm status may potentially interfere with those purposes, FINRA is not proposing to require the public disclosure of a firm's status as a Restricted Firm at this time. FINRA believes that it is necessary to gain meaningful experience with the proposed rule to evaluate the impact of creating an affirmative disclosure program.[159]

15. Economic Impact Assessment

Rockfleet commented that the proposal appears to be reverse engineered to target firms that FINRA has already chosen. As discussed above, the proposed Preliminary Criteria for Identification are based on metrics that are replicable and transparent to FINRA and the affected member firms, and are intended to identify firms that pose far greater risks to their customers than other firms. One identifier of these types of firms is that they and their brokers generally have substantially more Registered Person and Member Firm Events compared to their peers. This is consistent with a growing academic literature that provides evidence on past disciplinary and other regulatory events associated with a firm or individual being predictive of similar future events.[160] These patterns indicate a persistent, albeit limited, population of firms with a history of misconduct that may not be acting appropriately as a first line of defense to prevent customer harm by their brokers. Accordingly, the proposed rule is intended to strengthen FINRA's toolkit to respond to these firms and brokers with a significant history of misconduct based on a proposed criteria that relies on regulatory and other disclosure events, similar to those used in the literature.

FINRA also conducted several validations on the firms meeting the criteria, by reviewing the extent to which firms identified were subsequently expelled, associated with unpaid awards, or were associated with ''new'' Registered Person and Member Firm Events. For example, these validations showed that the identified firms had on average approximately 6.1–19.9 times more new disclosure events after their identification than other firms in the industry during the same period that would not have met the Preliminary Criteria for Identification. This suggests that the proposed criteria is effective in identifying firms that may be associated with additional events after identification, which is consistent with the literature's finding on regulatory events being predictive of similar future events.

Better Markets commented that the Economic Impact Assessment did not quantify the harm to investors when firms with a significant history of misconduct are permitted to continue engaging with investors. The proposed rule is intended to place additional restrictions on identified firms and increase scrutiny by these firms on their brokers. As a result, FINRA anticipates that the proposed rule will reduce the risk and associated costs of possible future customer harm and lead to improvements in the compliance culture, relative to the economic baseline of the current regulatory framework. The proposed rule is intended to create incentives for firms and brokers to limit or end practices that result in customer harm and provide increasing restrictions on those that choose not to alter their activities. Nonetheless, it is difficult to predict or quantify, before the proposed rule is implemented, the extent to which firms may continue to engage in harmful activities despite any additional restrictions imposed. However, FINRA plans to review the proposed rule after gaining sufficient experience with it, at which time FINRA will assess the rule's ongoing effectiveness and efficiency.

Westpark wrote that FINRA should analyze how many brokers who are currently licensed and in good standing would become ''unemployable'' if the proposed rule were approved. FINRA's Economic Impact Assessment of the proposed rule includes the economic impacts on firms hiring and registered persons seeking employment. For example, as discussed above, FINRA estimates that during the 2013–2019 review period only one to two percent of the registered persons had any qualifying events in their regulatory records. Accordingly, 98%–99% of the registered persons (with no qualifying events) should have no adverse economic impacts associated with their employment opportunities. Further, the vast majority of member firms, approximately 98%, would likely be able to employ most of the individuals seeking employment in the industry—including ones who have some disclosures—without coming close to meeting the Preliminary Criteria for Identification. Accordingly, FINRA believes that these anticipated economic impacts would likely be limited to a small proportion of registered persons and member firms, particularly in cases where registered persons with disclosures are seeking employment at firms at or near the Preliminary Criteria for Identification.

Westpark commented that FINRA should back-test the impact of the proposed rule to cover a period that was not a bull market. The economic impact assessment evaluated the proposed criteria over the 2013–2019 period. Because of the criteria's 5-year lookback period for adjudicated events, the evaluation included events that reached a resolution between 2009 and 2019, which includes the period of the global financial crisis.

16. Suggested Alternatives or Additional Measures

Several comments suggested alternatives to proposed Rule 4111. For example, several commenters suggested that FINRA improve how it uses its existing rules and programs. For example, Network 1 commented that FINRA's enforcement program is already a practical solution for addressing ''bad brokers.'' Brooklight suggested that FINRA try to solve for any gaps in its enforcement authority and processes that prevent FINRA from dealing with the ''few bad actors'' motivating the proposal. ASA wrote that FINRA should pursue the expulsion of firms that do not carry out their supervisory obligations and act in ways that harm customers, and impose immediate lifetime bans on those who engage in certain egregious acts, such as theft of customer funds. ASA further commented that FINRA ''has an obligation to penalize and, if necessary, revoke the licenses of bad actors,'' and

[157] Cetera, FSI.

[158] Better Markets, Massachusetts, NASAA, SIFMA, St. John's SOL.

[159] It should be noted that information about a firm's status as a Restricted Firm, and any restricted deposit it must maintain, could become publicly available through existing sources or processes. Such disclosures could occur, for example, through Form BD, Form CRS, or financial statements, or when a Hearing Officer's decision in an expedited proceeding is published pursuant to FINRA's publicity rule.

[160] *See supra* note 5.

that ''[i]f FINRA believes it lacks the authority or the tools necessary to stop the most egregious abuses, . . . then it should work with the . . . SEC, Congress and the industry to correct the problem.'' Joseph Stone commented that FINRA should continue focusing on firms' supervisory systems.

As explained above, FINRA has a number of current programs through which it strives to prevent and deter misconduct by member firms and the individuals they hire. These tools have been effective in identifying and addressing a range of misconduct by individuals and firms, and FINRA has continued to strengthen them. Despite FINRA's efforts, however, persistent compliance issues continue to arise in some member firms, as explained above. Thus, while FINRA continues to explore whether additional enhancements to existing programs, including relevant statutory or regulatory changes,[161] would help FINRA target firms or individuals that engage in serious misconduct with greater speed and effectiveness, FINRA believes there remains a strong need to equip FINRA with authority to address more proactively the current risks posed by the limited population of firms with a significant history of misconduct.

Some commenters proposed that, instead of a Restricted Deposit Requirement, FINRA should impose insurance or performance bond requirements,[162] create a national investor recovery pool funded from fines that FINRA receives [163] or a restitution fund,[164] or impose additional capital requirements on identified firms.[165] FINRA believes these alternatives present challenges and is continuing to propose a Restricted Firm Obligations Rule that would authorize the imposition of Restricted Deposit Requirements.

Some commenters proposed other alternatives for FINRA's consideration. Chiu wrote that FINRA should instead focus attention on investor education and encouraged the creation of more tools like the Senior Helpline. Colorado FSC recommended that FINRA assign ''disciplinary training and behavior restructuring'' to address disclosure related issues. FINRA does not believe, however, that the suggested alternatives would be as effective as the proposed Restricted Firm Obligations Rule at addressing firms with a significant history of misconduct and encouraging such firms to modify their behavior and risk profile.

Several commenters proposed steps that FINRA should take in addition to the proposal. These included: (1) Requiring firms to provide BrokerCheck reports to customers; [166] (2) expelling firms that are Restricted Firms for two consecutive years; [167] (3) ''de-licensing'' all current brokers who worked at such firms when they were initially designated as Restricted Firms; [168] (4) disclosing more information on BrokerCheck, such as the percentage of brokers at a firm with disclosures and the average number of brokers' and firm's disclosures,[169] or which brokers have a demonstrable pattern of violating the law; [170] and (5) explaining to investors the methods that ''recidivist'' firms employ.[171] Several commenters also suggested that FINRA give more consideration to proposing a rule like Investment Industry Regulatory Organization of Canada (IIROC) Consolidated Rule 9208, which is a terms and conditions rule.[172]

FINRA appreciates receiving suggestions on additional steps it might take to address firms with a significant history of misconduct, and FINRA will continue to explore ways to address firms with a significant history of misconduct. As FINRA explained in *Regulatory Notice* 19–17, this includes continuing to consider whether to propose a terms and conditions rule. FINRA notes, however, that some of Better Markets' suggestions essentially request that FINRA broaden the statutory definition of disqualified persons, which is not within FINRA's jurisdiction to do.[173]

17. Miscellaneous Comments Outside the Scope of the Proposal

Some commenters raised concerns regarding issues that are not directly related to the proposal, such as whether barring ''rogue brokers'' or firms is effective,[174] whether the Uniform Registration Forms should request disclosure of unsubstantiated allegations or unadjudicated alleged rule violations,[175] and whether FINRA Hearing Officers are impartial.[176] FINRA believes, however, that these comments are outside the scope of the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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–FINRA–2020–041 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–2020–041. This file number should be included on the subject line if email is used. To help the

[161] The Exchange Act includes fair procedure requirements for various SRO actions, including the disciplining of members and persons associated with members, and sets out the types of misconduct that presumptively exclude brokers from engaging in the securities business (identified as statutory disqualifications or ''SDs''). The Exchange Act and SEC rules thereunder also establish a framework within which FINRA evaluates whether to allow individuals who are the subject of a statutory disqualification. In addition, FINRA's review of many SD applications is governed by the standards set forth in *Paul Edward Van Dusen,* 47 SEC. 668 (1981), and *Arthur H. Ross,* 50 SEC. 1082 (1992). These standards provide that, in situations where an individual's misconduct has already been addressed by the SEC or FINRA, and certain sanctions have been imposed for such misconduct, FINRA should not consider the individual's misconduct when it evaluates an SD application.

[162] Brooklight, Cetera, Rockfleet.

[163] PIRC.

[164] Sichenzia.

[165] ASA.

[166] PIRC.

[167] Better Markets.

[168] Better Markets.

[169] St. John's SOL.

[170] Better Markets.

[171] Better Markets.

[172] Better Markets, Brooklight, Cambridge, Cetera, Luxor, Massachusetts, MIRC, PIRC.

[173] *See* 15 U.S.C. 78c(a)(39) (defining ''statutory disqualification'').

[174] Chiu.

[175] AdvisorLaw.

[176] Moss & Gilmore.

[177] 17 CFR 200.30–3(a)(12).

Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of 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–2020–041 and should be submitted on or before December 28, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[177]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–26594 Filed 12–3–20; 8:45 am]

BILLING CODE 8011–01–P

[177] 17 CFR 200.30–3(a)(12).

FEDERAL REGISTER

Vol. 85 Friday,

No. 234 December 4, 2020

Part IV

Department of the Treasury

31 CFR Part 33

Department of Health and Human Services

45 CFR Parts 147, 150, 153, et al.

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates To State Innovation Waiver (Section 1332 Waiver) Implementing Regulations; Proposed Rule

DEPARTMENT OF THE TREASURY

31 CFR Part 33

RIN 1505–AC72

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147, 150, 153, 155, 156, 158, and 184

[CMS–9914–P]

RIN 0938–AU18

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates To State Innovation Waiver (Section 1332 Waiver) Implementing Regulations

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health & Human Services (HHS), Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth payment parameters and provisions related to the risk adjustment program; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges and State-based Exchanges on the Federal platform. It includes proposed changes related to special enrollment periods; Navigator program standards; direct enrollment entities; the administrative appeals processes with respect to health insurance issuers and non-federal governmental group health plans; the medical loss ratio program; acceptance of payments by issuers of individual market Qualified Health Plans; and other related topics. It proposes clarifications to the regulation imposing network adequacy standards with regard to Qualified Health Plans that do not use provider networks. It proposes changes to the regulation requiring the reporting of certain prescription drug information by qualified health plans or their pharmacy benefit managers. It also proposes a new direct enrollment option for Federally-facilitated Exchanges and State Exchanges. This proposed rule also proposes changes related to section 1332 State Innovation Waivers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 30, 2020.

ADDRESSES: In commenting, please refer to file code CMS–9914–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9914–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9914–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Usree Bandyopadhyay, (410) 786–6650, Grace Bristol, (410) 786–8437, Kiahana Brooks, (301) 492–5229, or Ken Buerger, (410) 786–1190, for general information.

Cam Clemmons, (206) 615–2338, for matters related to health insurance reform requirements for the group and individual insurance markets and administrative appeals for health insurance issuers and non-federal governmental group health plans.

Allison Yadsko, (410) 786–1740, for matters related to risk adjustment.

Aaron Franz, (410) 786- 8027, for matters related to user fees.

Isadora Gil, (410) 786–4532, or Colleen Gravens, (301) 492–4107, for matters related to EDGE discrepancies.

Joshua Paul, (301) 492–4347, Renee O'Neill, (410) 786–8821, or Ruthanne Romero, (410) 786–8757, for matters related to risk adjustment data validation.

Dan Brown, (434) 995–5886, for matters related to web-brokers or direct enrollment, other than the direct enrollment option for Federally-facilitated and State Exchanges.

Robert Yates, (301) 492–5151, for matters related to the direct enrollment option for Federally-facilitated and State Exchanges.

Emily Ames, (301) 492–4246, for matters related to termination notices.

Marisa Beatley, (301) 492–4307, for matters related to employer-sponsored coverage verification.

Carolyn Kraemer, (301) 492–4197, for matters related to special enrollment periods for Exchange enrollment under part 155.

Katherine Bentley, (301) 492–5209, for matters related to special enrollment period verification.

Ken Buerger, (410) 786–1190, for matters related to EHB-benchmark plans, defrayal of state-required benefits, network adequacy standards, and PBM transparency reporting requirements.

Joshua Paul, (301) 492–4347, for matters related to the premium adjustment percentage.

Adrianne Carter, (303) 844–5810, or Amber Bellsdale, (301) 492–4411, for matters related to disputes under 45 CFR 156.1210.

Leigha Basini, (301) 492–4380, for matters related to acceptance of payments by QHP issuers.

Nidhi Singh Shah, (301) 492–5110, for matters related to the Quality Rating System and the Qualified Health Plan Enrollee Experience Survey.

Alper Ozinal, (301) 492–4178, for matters related to financial program audits and civil money penalties.

Adrianne Patterson, 410–786–0696, for matters related to netting of payments under 45 CFR 156.1215 and administrative appeals under 45 CFR 156.1220.

Christina Whitefield, (301) 492–4172, for matters related to the MLR program.

Lina Rashid, (443) 902–2823, Michelle Koltov, (301) 492–4225, or Kimberly Koch, (202) 622–0854 for matters related to State Innovation Waivers.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Table of Contents

I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges,'' are entities established under the Patient Protection and Affordable Care Act (PPACA) [1] 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-Exchange.

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 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 proposed rule, within the limitations of current law, we propose 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 proposed rule, we propose to amend some of these provisions and parameters, with a focus on maintaining a stable regulatory environment. These proposed changes would provide issuers with greater predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs. The proposals would also provide states with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability.

Risk adjustment continues to be a core program in the individual and small group markets both on and off Exchanges, and some of the major proposals in this rule include proposed recalibrated parameters for the HHS-operated risk adjustment methodology. We also propose changes to the risk adjustment models to include a two-stage specification in the adult and child models, add severity and transplant indicators interacted with hierarchical condition category (HCC) counts factors to the adult and child models, and modify the enrollment duration factors in the adult models. Additionally, we propose to allow states to request multi-year state risk adjustment transfer reductions of up to 3 years, as well as clarifications to the process for HHS to audit and conduct compliance reviews of issuers of risk adjustment covered plans and reinsurance-eligible plans.

As we do every year in the HHS notice of benefit and payment parameters, we propose updated parameters applicable in the individual and small group markets. We propose the 2022 benefit year user fee rates for issuers offering plans through the Exchanges using the Federal platform. We propose lowering the Federally-facilitated Exchange (FFE) and State-based Exchange on the Federal platform (SBE–FP) user fees rates to 2.25 and 1.75 percent of total monthly premiums, respectively, in order to reflect enrollment, premium and HHS contract estimates for the 2022 plan year. We also propose user fee rates of 1.5 percent of total monthly premiums for FFE and SBE–FP states that elect the proposed direct enrollment option discussed later in the preamble.

In addition, we propose the 2022 benefit year premium adjustment percentage, required contribution percentage, and maximum annual limitations on cost sharing, including those for cost-sharing reduction (CSR) plan variations. These updates, required by law, will raise the annual limit on cost sharing for 2022 relative to the annual limit on cost sharing for 2021, thereby increasing cost sharing and out-of-pocket spending for consumers who will incur total costs close to the annual cost-sharing limit in the 2022 benefit year. For the 2023 benefit year and beyond, we also propose to publish these parameters in guidance annually, and if not in guidance, in the annual notice of benefit and payment parameters. Additionally, we propose clarifications to the process under which HHS audits QHP issuers related to advance payments of the premium tax credit (APTC), CSRs, and user fees.

We propose changes to the information that FFE-registered web-brokers are required to display on their websites. In addition, we propose amendments to codify more detail describing the operational readiness reviews that must be successfully completed as a prerequisite to a web-broker's non-Exchange website being approved for use by consumers to complete an Exchange eligibility application or a QHP selection. We similarly propose to add additional detail about the operational readiness reviews applicable to direct enrollment entities.

Stable and affordable Exchanges with healthy risk pools are necessary for

[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 proposed rule, we refer to the two statutes collectively as the ''Patient Protection and Affordable Care Act'' or ''PPACA''.

ensuring consumers maintain stable access to health insurance options. In order to minimize the potential for adverse selection in the Exchanges, we are sharing our future plans for rulemaking under which we will propose requirements related to Exchange verifications of whether applicants for QHP coverage with APTC or CSR have access to employer sponsored coverage that is affordable and offers minimum value. Until we engage in future rulemaking, we propose to extend our current enforcement posture under which Exchanges may exercise flexibility not to implement 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.

We propose new rules related to special enrollment periods. In addition, we propose to require Exchanges to conduct special enrollment period verification for at least 75 percent of new enrollments through special enrollment periods granted to consumers not already enrolled in coverage through the applicable Exchange.

We also propose minor procedural changes to provisions regarding administrative hearings in parts 150 and 156 to align with the Departmental Appeals Board's current practices for administrative hearings to appeal civil money penalties (CMPs).

We propose to release additional data from the QHP Enrollee Experience Survey (QHP Enrollee Survey). We also solicit comments on potential changes to the framework for the Quality Rating System (QRS) to support alignment with other CMS quality reporting programs and to further balance the individual survey and clinical quality measures on the overall quality scores. We are considering ways to modify the hierarchical structure for the QRS, which is how the measures are organized together for maximum simplicity and understanding of the quality rating information provided by the QRS.

We propose revisions to the regulations requiring the collection of certain prescription drug data from QHP issuers, and propose to implement a requirement for the reporting of this data from pharmacy benefit managers (PBMs) when a QHP issuer contracts with a PBM to administer its prescription drug benefit.

We propose to further regulate the standards related to QHP issuers' acceptance of payments for premiums and cost sharing. We also propose to make clarifications to the network adequacy rules to reflect that § 156.230 does not apply to indemnity plans seeking QHP certification.

We propose to establish a new direct enrollment option under which a State Exchange, State-based Exchange on the Federal platform or an FFE state (through an agreement with HHS) can leverage the potential of direct enrollment to offer consumers an enhanced QHP shopping experience. Under this option, instead of operating a centralized enrollment website, states could use direct enrollment technology to establish direct pathways to QHP issuers and web-brokers, through which consumers would apply for and enroll in a QHP and receive a determination of eligibility for APTC and CSRs.

We propose to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for medical loss ratio (MLR) reporting and rebate calculation purposes. We additionally propose to explicitly allow issuers the option to prepay a portion or all of the estimated MLR rebate for a given MLR reporting year in advance of the deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and the filing of the MLR Annual Reporting Form, and propose to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of any remaining rebates owed after prepayment until the following MLR reporting year. We also propose to allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules currently provide. Lastly, we propose to clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a public health emergency (PHE) declared by the Secretary of HHS in the 2021 benefit year and beyond, when such credits are permitted by HHS.

In this proposed rule, the Secretaries of HHS and the Department of the Treasury propose to reference and incorporate specific guidance published in the **Federal Register** in order to give states certainty regarding the requirements to receive and maintain approval by the Departments for State Innovation Waivers under section 1332 of the PPACA.

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 [2] and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.

Section 2702 of the PHS Act, as added by the PPACA, establishes requirements for guaranteed availability of coverage in the group and individual markets, including qualifying events that trigger special enrollment periods under section 2702(b) of the PHS Act.[3]

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 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group insurance market requirements contained in Part A of title XXVII of the PHS Act with respect to health insurance issuers when a state does not have authority to enforce or fails to substantially enforce these provisions and with respect to group health plans that are non-federal governmental plans.

Section 1301(a)(1)(B) of the PPACA directs all issuers of QHPs to cover the Essential Health Benefit (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

[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] Before enactment of the PPACA, HIPAA amended the PHS Act (formerly section 2711) to generally require guaranteed availability of coverage for employers in the small group market.

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 AV requirements. Section 1302(b) of the PPACA 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.

To set cost-sharing limits, 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: (1) The maximum annual limitation on cost sharing (section 1302(c)(1) of the PPACA); (2) the required contribution percentage used to determine whether an individual can afford minimum essential coverage (MEC) (section 5000A of the Internal Revenue Code of 1986 (the Code), as enacted by section 1501 of the PPACA); and (3) the employer shared responsibility payment amounts (section 4980H of the Code, as enacted by section 1513 of the PPACA).

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.

Sections 1311(b) and 1321(b) of the PPACA provide that each state has the opportunity to establish an individual market Exchange that facilitates the purchase of insurance coverage by qualified individuals through QHPs and meets other standards specified in the PPACA. Section 1321(c)(1) of the PPACA directs the Secretary to establish and operate such Exchange within states that do not elect to establish an Exchange or, as determined by the Secretary on or before January 1, 2013, will not have an Exchange operable by January 1, 2014.

Section 1311(c)(1) of the PPACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs, including network adequacy standards at section 1311(c)(1)(B) of the PPACA. Section 1311(d) of the PPACA describes the minimum functions of an Exchange. 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)(1) 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.[4]

Section 1311(c)(3) of the PPACA directs the Secretary to develop a system to rate QHPs offered through an Exchange, based on relative quality and price. 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 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 Exchanges to provide this quality rating information[5] to individuals and employers on the Exchange's website.

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.

Section 1312(e) of the PPACA directs the Secretary to establish procedures under which a state may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange and to assist individuals in applying for financial assistance for QHPs sold through an Exchange.

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-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. Office of Management and Budget (OMB) Circular 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(c)(2) of the PPACA provides that the provisions of section 2723(b) of the PHS Act shall apply to the enforcement of the Federal Exchange standards and authorizes the Secretary to enforce the Exchange standards using CMPs on the same basis as detailed in section 2723(b) of the PHS Act.

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 1332 of the PPACA provides the Secretary of HHS and the Secretary of the Treasury (collectively, the Secretaries) with the discretion to approve a state's proposal to waive specific provisions of the PPACA, provided the state's section 1332 waiver plan meets certain requirements. The Department of Health and Human Services and the Department of the

[4] 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 PPACA.

[5] The term ''quality rating information'' includes the 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'').

Treasury (collectively, the Departments) finalized implementing regulations on February 27, 2012 (76 FR 13553) and published detailed guidance on the Department's application of section 1332 to proposed state waivers on October 24, 2018 (83 FR 53575).

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 QHPs offered through the individual market Exchanges. This section also provides for reductions in cost sharing for American 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) of the PPACA 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 Secretary of the Treasury, the Secretary of Homeland Security, 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 use or disclosure 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.

Section 5000A of the Code, as added by section 1501(b) of the PPACA, requires individuals to have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act (Pub. L. 115–97, December 22, 2017) the individual shared responsibility payment has been reduced to $0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under 45 CFR 155.305(h) or 45 CFR 156.155.

Section 1150A(a) of the Social Security Act (the Act) requires a health benefits plan or PBM that manages prescription drug coverage under a contract with a QHP issuer to provide certain prescription drug information to the Secretary at such times, and in such form and manner, as the Secretary shall specify. HHS will limit disclosure of the information disclosed by a health benefits plan or PBM under this section as required by section 1150A of the Act and may only disclose the information in a form which does not disclose the identity of a specific PBM or plan, or prices charged for specific drugs, except that for limited purposes, HHS may disclose the information to states to carry out section 1311 of the PPACA. An issuer or PBM that fails to provide the information on a timely basis or that knowingly provides false information may be subject to a civil monetary penalty under section 1927(b)(3)(C) of the Act in the same manner as such provisions apply to a manufacturer with an agreement under that section.

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 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 2015 fiscal year 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 HHS–RADV process (proposed 2018 Payment Notice). We published the 2018

[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.

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 HHS–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 **Federal Register** (77 FR 17220 through 17252) and in the March 8, 2016 **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 **Federal Register** (77 FR 17219) and in the December 22, 2016 **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 **Federal Register** (77 FR 17219) and the December 22, 2016 **Federal Register** (81 FR 94058). 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 HHS–RADV audits. We published the 2020 Payment Notice final rule in the April 25, 2019 **Federal Register** (84 FR 17454).

In the February 6, 2020 **Federal Register** (85 FR 7088), we published a proposed rule that included updates to the in the risk adjustment models' HCCs and a modification HHS–RADV error rate calculation methodology. We published the 2021 Payment Notice final rule in the May 14, 2020 **Federal Register** (85 FR 29164).

In the June 2, 2020 **Federal Register** (85 FR 33595), we published a proposed rule that proposed updates to various aspects of the HHS–RADV methodologies and processes. These updates included revisions to the HCC failure rate grouping algorithm, the introduction of a sliding scale adjustment in HHS–RADV error rate calculation, the introduction of a constraint on risk score adjustments for low-side failure rate outliers, and the transition from the prospective application of HHS–RADV adjustments to an application of HHS–RADV results to risk scores from the same benefit year as that being audited.

In the September 2, 2020 **Federal Register** (85 FR 54820), HHS issued an interim final rule containing certain policy and regulatory revisions in response to the COVID–19 PHE, wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year (interim final rule on COVID–19).

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 December 27, 2019 **Federal Register** (84 FR 71674), we published a final rule that revised standards relating to oversight of Exchanges established by states and periodic data matching frequency.

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 PPACA health insurance market reforms that became effective in 2014 was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing those provisions 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 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. In the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 17058), we clarified that certain exceptions to the special enrollment periods only apply with respect to coverage offered outside of the Exchange in the individual market.

[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.*

4. Administrative Appeals Process Related to Federal Enforcement in Group and Individual Health Insurance Markets and Non-Federal Governmental Group Health Plans

On April 8, 1997 an interim final rule with comment period was published in the **Federal Register** (62 FR 16894) that implemented the HIPAA health insurance reforms by adding 45 CFR parts 144, 146, and 148. Included in those regulations were enforcement provisions. In the June 10, 1997 **Federal Register** (62 FR 31669), we published technical corrections to these interim final rules. After gaining some experience with direct federal enforcement in some states, we determined that it was necessary to provide more detail on the procedures that will be used to enforce HIPAA when a state does not do so. On August 20, 1999, an interim final rule with comment period was published in the **Federal Register** (64 FR 45786) that provided more detail on the procedures for enforcing title XXVII of the PHS Act, as added by HIPAA, and as amended by the Mental Health Parity Act of 1996 (Pub. L. 104–204, September 26, 1996), the Newborns' and Mothers' Health Protection Act of 1996 (Pub. L. 104–204, September 26, 1996), and the Women's Health and Cancer Rights Act of 1998 (Pub. L. 105–277, October 21, 1998), when a state does not enforce such laws. We published a final rule on November 25, 2005 in the **Federal Register** (70 FR 71020) that finalized this interim final rule, and made non-substantive amendments to the regulations detailing procedures for enforcing title XXVII of the PHS Act.

5. 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. In the July 15, 2011 **Federal Register** (76 FR 41865), we published a proposed rule with proposals 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 the May 11, 2016 **Federal Register** (81 FR 29146), we published an interim final rule with 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 March 8, 2016 **Federal Register** (81 FR 12203), the final 2017 Payment Notice codified State Exchanges on the Federal platform along with relevant requirements. 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. In the May 14, 2020 **Federal Register** (85 FR 29204), the 2021 Payment Notice final rule made certain changes to plan category limitations and special enrollment period coverage effective date rules, allowed individuals provided a non-calendar year qualified small employer health reimbursement arrangement (QSEHRA) to qualify for an existing special enrollment period, and discussed plans for future rulemaking for employer-sponsored coverage verification and non-enforcement discretion for Exchanges that do not conduct random sampling until plan year 2021.

6. Essential Health Benefits

On December 16, 2011, HHS released a bulletin [9] 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.

The 2015 Payment Notice final rule, established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage. 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 National Health Expenditure Accounts (NHEA), which are calculated by the CMS Office of the Actuary. In the 2020 Payment Notice final rule, we amended the methodology for calculating the premium adjustment percentage by estimating per capita insurance premiums as private health insurance premiums, minus premiums paid for Medigap insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees. Additionally, in response to public comments to the proposed 2021 Payment Notice, the 2021 Payment Notice final rule included a policy stating that we will finalize payment parameters that depend on NHEA data, including the premium adjustment percentage, based on the data that are available as of the publication of the proposed rule for that benefit year, even if NHEA data are updated between the proposed and final rules.

In a proposed rule published in the July 15, 2020 **Federal Register** (85 FR 42782), HHS, along with the Departments of Labor and the Treasury, proposed using the premium adjustment percentage as one alternative in setting the parameters for permissible increases in fixed-amount cost-sharing requirements for grandfathered group health plans.

7. 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 on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was

[9] ''Essential Health Benefits Bulletin,'' December 16, 2011. Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

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), the April 17, 2018 **Federal Register** (83 FR 16930), the May 14, 2020 **Federal Register** (85 FR 29164) and an interim final rule was published in the September 2, 2020 **Federal Register** (85 FR 54820).

8. Quality Rating System and Enrollee Satisfaction Survey

The overall framework and elements of the rating methodology for the QRS were published in the November 19, 2013 **Federal Register** (78 FR 69418). Consistent with statutory provisions, in May 2014, HHS issued regulations at §§ 155.1400 and 155.1405 to establish the 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.[10] 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.[11]

9. State Innovation Waivers

Section 1332(a)(4)(B) of the PPACA requires the Secretaries to issue regulations regarding procedures for State Innovation Waivers. On March 14, 2011, the Departments published the ''Application, Review, and Reporting Process for Waivers for State Innovation'' proposed rule[12] in the **Federal Register** (76 FR 13553) to implement section 1332(a)(4)(B) of the PPACA. On February 27, 2012, the Departments published the ''Application, Review, and Reporting Process for Waivers for State Innovation'' final rule[13] in the **Federal Register** (77 FR 11700) (hereinafter referred to as the ''2012 Final Rule''). On October 24, 2018, the Departments issued the ''State Relief and Empowerment Waivers'' guidance[14] in the **Federal Register** (83 FR 53575) (hereinafter referred to as the ''2018 Guidance''), which superseded the previous guidance[15] published on December 16, 2015 in the **Federal Register** (80 FR 78131) and provided additional information about the requirements that states must meet for waiver proposals, the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. On November 6, 2020, the Departments issued an interim final rule[16] in the **Federal Register** (85 FR 71142), which revises regulations to set forth flexibilities in the public notice requirements and post-award public participation requirements for State Innovation Waivers under section 1332 of the PPACA during the COVID–19 PHE.

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges and the risk adjustment and HHS–RADV programs. We have held a number of listening sessions with consumers, providers, employers, health plans, advocacy groups and the actuarial community to gather public input. We have solicited input from state representatives on numerous topics, particularly risk adjustment and the direct enrollment option for FFEs and State Exchanges.

We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states, and 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 proposed rule.

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 147, 150, 153, 155, 156, 158, and 184. In addition, the regulations outlined in this proposed rule governing State Innovation Waivers under section 1332 of the PPACA at 45 CFR part 155 subpart N would also be codified in 31 CFR part 33.

The proposed changes to 45 CFR part 147 would make technical and conforming amendments regarding limited and special enrollment periods in the individual market.

The proposed changes to 45 CFR part 150 would make minor procedural changes to the requirements for administrative appeals of CMPs by health insurance issuers and non-federal governmental group health plans to align with current practices for the Departmental Appeals Board. We propose to make parallel changes to the requirements for administrative appeals of CMPs by QHP issuers under 45 CFR part 156, subpart J.

The proposed changes to 45 CFR part 153 would recalibrate the HHS risk adjustment models consistent with the approach outlined in the 2020 Payment Notice to transition away from the use of MarketScan® data. However, we propose to use the enrollee-level EDGE data from 2016, 2017 and 2018, the same data used for the 2021 model recalibration. We also propose changes to the HHS risk adjustment models to include a two-stage specification in the adult and child models, add severity and transplant indicators interacted with HCC counts factors in the adult and child models, and modify the enrollment duration factors in the adult models. In addition, we propose to clarify risk adjustment reporting requirements for issuers that choose to offer premium credits, if permitted by HHS for future benefit years. In order to provide greater market predictability, we propose to allow states to request a reduction of risk adjustment transfers for multiple years and set forth the request from Alabama to reduce risk adjustment transfers for the 2022 benefit year. Additionally, we propose clarifications to the process for HHS to audit issuers of risk adjustment covered plans and reinsurance-eligible plans and also propose to establish authority for HHS to conduct compliance reviews of these issuers. The proposals in part 153

[10] 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 QRS star 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.*

[11] See, for example, ''Center for Clinical Standards & Quality, CMS, The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2021,'' September 2020. Available at *https://www.cms.gov/files/document/quality-rating-system-and-qualified-health-plan-enrollee-experience-survey-technical-guidance-2021.pdf.*

[12] *https://www.govinfo.gov/content/pkg/FR-2011-03-14/pdf/2011-5583.pdf.*

[13] *https://www.govinfo.gov/content/pkg/FR-2012-02-27/pdf/2012-4395.pdf.*

[14] *https://www.govinfo.gov/content/pkg/FR-2018-10-24/pdf/2018-23182.pdf.*

[15] *https://www.govinfo.gov/content/pkg/FR-2015-12-16/pdf/2015-31563.pdf.*

[16] *https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency.*

also relate to the risk adjustment user fee for the 2022 benefit year. We also propose to revise the schedule for the collection of HHS–RADV charges and disbursement of payments such that these charges and disbursements will occur in the same calendar year in which HHS–RADV results are released. Finally, the proposals regarding part 153 include a proposal to shorten the discrepancy reporting windows for HHS–RADV, update the applicable regulations regarding when second validation audit (SVA) findings can be disputed or appealed, expand the conflict of interest standard for IVA Entities, and codify two previously established exemptions from the requirement to participate in HHS–RADV.

We propose to amend the definition of direct enrollment technology provider and add a definition of QHP issuer direct enrollment technology provider in part 155 to recognize that QHP issuers may also use QHP issuer direct enrollment technology providers to facilitate participation in direct enrollment under §§ 155.221 and 156.1230, and make conforming amendments to the definition of web-broker. We also propose changes to web-broker website display requirements, and propose to codify more specific operational readiness review requirements for web-brokers and direct enrollment entities. In addition, we propose allowing Navigators and certified application counselors (CACs) to assist consumers with applying for eligibility for insurance affordability programs and QHP enrollment through web-broker non-Exchange websites under certain circumstances. We also propose to amend the marketing and display requirements for direct enrollment entities.

We also propose to establish a new direct enrollment option for State Exchanges, SBE–FPs and FFE states to use direct enrollment technology and non-Exchange websites developed by approved web brokers, issuers and other direct enrollment partners to enroll qualified individuals in QHPs offered through the Exchange.

We also propose several amendments to special enrollment period policy. Specifically, we propose: To add a new flexibility to allow current Exchange enrollees and their dependents to change to a QHP of a lower metal level if they qualify for a special enrollment period due to becoming newly ineligible for APTC; to allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred to select a plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event; and to clarify that a special enrollment period is triggered when a qualified individual or his or her dependent is enrolled in COBRA continuation coverage, and the employer contributions for such coverage completely cease. We also propose to require Exchanges to verify eligibility for at least 75 percent of special enrollments for consumers newly enrolling in Exchange coverage.

As we do every year in the annual HHS notice of benefit and payment parameters, we propose to update 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. Additionally, we propose to amend part 156 to establish that for the 2023 benefit year and beyond, we will publish the annual updates to the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing and required contribution percentage in guidance in January of the benefit year prior to the applicable benefit year, rather than in the applicable benefit year's annual HHS notice of benefit and payment parameters, as long as no change to the methodologies to calculate these amounts are proposed. We also propose a methodology for analyzing the impact of preliminary values of the reduced annual maximum limitations on cost sharing on the AVs of silver plan variations. Additionally, we propose clarifications to the process for HHS to audit QHP issuers related to APTC, CSRs, and user fees and propose to establish authority for HHS to conduct compliance reviews to ensure compliance with Federal APTC, CSRs, and user fee standards. We propose to update the user fee rates for the 2022 benefit year for all issuers participating on the Exchanges using the Federal platform. We also propose modifications to the regulations addressing network adequacy standards for non-network plans and payments accepted by QHP issuers. Finally, we propose to require QHP issuers to accept premium payments made on behalf of an enrollee from an individual coverage health reimbursement arrangement (individual coverage HRA) or QSEHRA.

The proposed changes to part 158 would establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes. The proposed changes to part 158 would also explicitly allow issuers the option to prepay a portion or all of the estimated MLR rebate for a given MLR reporting year in advance of the deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and filing the MLR Annual Reporting Form, and establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. In addition, the proposed changes to part 158 would allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules currently provide. Lastly, we propose to clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond when such credits are permitted by HHS.

The proposed addition of part 184 would require PBMs under contract with an issuer of QHPs to report prescription drug data required by section 1150A of the Act.

The proposed changes in 31 CFR part 33 and 45 CFR part 155 related to State Innovation Waivers would reference and incorporate the existing 2018 Guidance into regulations in order to give states certainty regarding the requirements to receive and maintain approval by the Departments.

III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2022—Department of Health and Human Services

A. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Guaranteed Availability of Coverage (§ 147.104)

Section 147.104(b)(2) incorporates by reference certain Exchange special enrollment periods described in § 155.420, making those special enrollment periods applicable to non-grandfathered coverage offered in the individual market through or outside of an Exchange. We propose amendments to § 147.104(b)(2) to clarify that paragraph (b)(2)(ii) does not apply to references in § 155.420(d)(4) (relating to errors of the Exchange), and to make a conforming amendment consistent with the proposal in § 155.420(c)(5) relating to special enrollment period availability for individuals who do not receive timely notice of a triggering event.

Section 155.420(d)(4) establishes an Exchange special enrollment period for a qualified individual or their

dependent if their enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, misconduct, or inaction of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-Exchange entity providing enrollment assistance or conducting enrollment activities. Section 147.104(b)(2)(ii) states that, when determining the application of a special enrollment period for individual market coverage offered outside the Exchange, a reference in § 155.420 to a ''QHP'' is deemed to refer to a plan, a reference to ''the Exchange'' is deemed to refer to the applicable state authority, and a reference to a ''qualified individual'' is deemed to refer to an individual in the individual market.

However, this paragraph was not intended to apply to § 155.420(d)(4), which is specific to errors of the Exchange, not the applicable state authority. It would be inappropriate for the triggering event in this case to apply to errors of the applicable state authority because the state does not perform the same functions as the Exchange. For example, the state authority does not perform an enrollment function. Thus, basing the triggering event on errors of the state is inappropriate and could create different special enrollment periods in the individual market on and off of the Exchange.

Therefore, we propose to clarify that § 147.104(b)(2)(ii) does not apply to references in § 155.420(d)(4). As a result, issuers offering health insurance coverage in the individual market must provide a limited open enrollment period under the same circumstances as described in § 155.420(d)(4).

In addition, we propose a conforming amendment to § 147.104(b)(4)(ii), consistent with the proposal in § 155.420(c)(5), to establish that if an individual did not receive timely notice of a triggering event described in paragraph (b)(2) or (3) of § 147.104, and otherwise was reasonably unaware that such a triggering event occurred, an issuer of non-grandfathered coverage in the individual market, whether inside or outside an Exchange, must assign the date the individual knew, or reasonably should have known, of the occurrence of the triggering event as the date of the triggering event for a special enrollment period. Consistent with §§ 147.104(b)(5) and 155.420(b), this proposal would allow the individual or dependent to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event or another effective date that would otherwise be available pursuant to § 155.420(b). We solicit comments on this approach. We note that this rule would not apply for special enrollment periods in the group market, and seek comment on whether we should exclude the reference to the triggering events in § 147.104(b)(3) in the amended § 147.104(b)(4)(ii) in order to retain alignment of the individual and group market special enrollment periods required under § 147.104(b)(3).

B. Part 150—CMS Enforcement in Group and Individual Markets

1. Technical Corrections

Part 150 sets forth our enforcement processes for all the requirements of title XXVII of the PHS Act with respect to health insurance issuers and non-federal governmental group health plans. This proposed rule would make technical corrections to multiple sections of part 150. Specifically, we propose removing all references to ''HIPAA'' and replacing them with ''PHS Act'' to clarify that the part 150 processes are used for enforcing not only the requirements emanating from HIPAA, but also the PPACA and other legislation enacted subsequent to HIPAA. These proposed wording changes were made in the February 27, 2013 **Federal Register** final rule entitled ''Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review'' (78 FR 13406). However, because of an oversight, some references were not updated at that time. In this rule, we propose this change to the definition of ''Complaint'' in § 150.103; the introductory text to § 150.303(a), as well as to §§ 150.205(e)(2); 150.213(b); 150.305(a)(1), (a)(2), (b)(1) and (c)(1); 150.311(g) and 150.313(b).

2. Administrative Hearings

Additionally, we propose certain procedural changes to part 150 sections regarding administrative hearings. These proposed changes are intended to align with the Departmental Appeals Board's current practices for administrative hearings to appeal CMPs. Specifically, we propose changes that would remove requirements to file submissions in triplicate and instead require electronic filing. This change is reflected in the proposed amendments to the definition of ''Filing date'' in § 150.401, to the introductory text in § 150.427(a), and to the service of submission requirements captured in § 150.427(b). We also propose amendments to several provisions in part 150 to allow for the option of video conferencing as a form of administrative hearing in part 150 in addition to the forms already allowed. To capture this flexibility, we propose amendments to the definition of ''Hearing'' in § 150.401 and to the requirements outlined in § 150.419(a) related to the forms for the hearing, § 150.441(e) related to prehearing conferences, and § 150.447(a) related to the record of the hearing. Finally, we propose to update § 150.431 to allow the Administrative Law Judge (ALJ) to communicate the next steps for a hearing in either the acknowledgement of a request for hearing or on a later date. We propose parallel amendments to the administrative hearings requirements under subpart J of part 156. We seek comment on these proposals.

C. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

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.[17] 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.[18] We did not receive any requests from states to operate risk adjustment for the 2022 benefit year; therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2022 benefit year.

We propose changes in this rule to the identification of the 3 benefit years of enrollee-level EDGE data that would be used for purposes of the annual recalibration of the risk adjustment models. We also propose modeling updates to improve the models' predictive power for certain subgroups of enrollees, as well as proposed changes to the enrollment duration factors for the adult models, and we propose to continue a pricing adjustment related to the Hepatitis C drugs. We propose to allow states to submit multi-year requests for reductions to transfer calculations under the state payment transfer formula and we outline the 2022 benefit year reduction request submitted by Alabama. Additionally, we propose to clarify risk adjustment reporting requirements for issuers that choose to

[17] 42 U.S.C. 18063.

[18] Also see 42 U.S.C. 18041(c)(1).

offer premium credits, if permitted by HHS for future benefit years. We propose the risk adjustment user fee for the 2022 benefit year and propose to codify in regulation the previously established exemptions from HHS–RADV requirements for issuers with only small group market carryover coverage in the benefit year being audited and for sole issuers in a state market risk pool during the benefit year being audited. We also propose to revise the schedule for the collection of HHS–RADV charges and disbursement of payments such that these charges and disbursements will occur in the same calendar year in which HHS–RADV results are released. Finally, we propose to shorten the discrepancy reporting windows during HHS–RADV, clarify and expand the conflict of interest standards that will be applied to initial validation audit (IVA) entities, and update the risk adjustment regulations to more clearly reflect the limitations on the ability to dispute or appeal SVA findings.

1. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as hierarchical condition categories (HCCs)), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and 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.[19] 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 state transfer 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.

a. Updates to Data Used for Risk Adjustment Model Recalibration

Consistent with the approach outlined in the 2020 Payment Notice to no longer rely upon MarketScan® data[20] for recalibrating the risk adjustment models, we propose to continue to recalibrate the risk adjustment models for the 2022 benefit year using only enrollee-level EDGE data. However, rather than using 2017, 2018 and 2019 enrollee-level EDGE data, we propose to use the 2016, 2017, and 2018 enrollee-level EDGE data (the same years' data used to recalibrate the 2021 risk adjustment models) to recalibrate the risk adjustment models for the 2022 benefit year. We also propose to continue to use blended, or averaged, coefficients from the 3 years of separately solved models for the 2022 benefit year model recalibration.

Previously, we used the 3 most recent years of MarketScan® data available to recalibrate the 2016, 2017, and 2018 benefit year risk adjustment models. Then, starting with the 2019 benefit year, we began transitioning from using the MarketScan® data to using the enrollee-level EDGE data to recalibrate the risk adjustment models. The 2021 benefit year was the first year that we recalibrated the risk adjustment models using 3 years of enrollee-level EDGE data.[21] Specifically, for the 2021 benefit year, we used the 2016, 2017, and 2018 benefit years of enrollee-level EDGE data to recalibrate the risk adjustment models. During 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. In some prior years, this approach resulted in reliance on data that could not be incorporated into the coefficients until after the publication of the applicable benefit year's Payment Notice, because the associated data was not available in time to incorporate into the models in time for publication in the Payment Notice.[22] For example, due to the timing of the proposed 2021 Payment Notice, we were unable to incorporate the 2018 benefit year enrollee-level EDGE data into the proposed coefficients in the proposed 2021 Payment Notice, and instead included draft coefficients in the proposed rule reflecting only 2016 and 2017 benefit years' enrollee-level EDGE data.[23] We were also unable to incorporate the 2018 benefit year enrollee-level EDGE data in the final coefficients in the 2021 Payment Notice; therefore, consistent with § 153.320(b)(1)(i), we released the final 2021 benefit year coefficients in guidance after publication of the 2021 Payment Notice.[24] We followed a similar approach in other benefit years when we were unable to incorporate the most recent year of available data in the applicable benefit year's Payment Notice.[25]

Some commenters to the proposed 2021 Payment Notice expressed concern about when the final blended coefficients would be available, asking that final coefficients be made available earlier. Having the risk adjustment coefficients for the upcoming benefit year available earlier allows issuers more time to incorporate this information when pricing their plans for the upcoming benefit year. Commenters offered suggestions for ways HHS could propose coefficients using all of the data years that HHS would use for the final coefficients. Stakeholders submitted similar comments in prior years when the final coefficients were released in guidance after publication of the applicable benefit year's Payment Notice.[26] We have continued to consider these comments and, in this rulemaking, we propose to change our approach for identifying the 3 most recent years of enrollee-level EDGE data that would be used to recalibrate the risk adjustment models. Previously, we used the three most recent years of data that are available in time for publication in the final rule or soon thereafter in guidance. However, beginning with the 2022 benefit year, we are proposing to

[19] For the 2018 benefit year, there were 12 RXCs, but starting with the 2019 benefit year, the two severity-only RXCs were removed from the adult risk adjustment models. See, for example, 83 FR 16941.

[20] 84 FR 17463 through 17466.

[21] 85 FR 29173 through 29175.

[22] See, for example, the 2018 Payment Notice final rule, 81 FR 94058; and the 2021 Payment Notice final rule, 85 FR 29173 through 29175.

[23] See 85 FR 7097 through 7098 and 7104 through 7112.

[24] See 85 FR 29173 through 29175. Also see *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

[25] See, for example, the 2018 Payment Notice rule, 81 FR 94084. Also see *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/2018-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

[26] See, for example, 81 FR 94084 through 94085.

use the 3 most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating the data in the draft recalibrated coefficients published in the proposed rule and we propose to not update the coefficients between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available for incorporation. The purpose of this proposed change is to respond to stakeholders' request to provide the proposed coefficients in the proposed rule while continuing to use the 3 most recent consecutive years of enrollee-level EDGE data available to recalibrate the risk adjustment models. We believe this approach promotes stability and avoids the delays in publication of the coefficients while continuing to develop blended, or averaged, coefficients from the 3 years of separately solved models for model recalibration. This proposed approach also would continue to use actual data from issuers' individual and small group (or merged) market populations, as well as maintain year-to-year stability in risk scores as the recalibration would continue to use at least two years of enrollee-level EDGE data that were used in the previous year's models.[27]

For these reasons, we propose to use 2016, 2017, and 2018 benefit years' enrollee-level EDGE data for the 2022 benefit year model recalibration. We seek comment on our proposal to determine coefficients for the 2022 benefit year based on a blend of separately solved coefficients from the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data and our proposed approach to identify the 3 most recent years of data available for the annual recalibration of the risk adjustment models moving forward. Additionally, we seek comment on whether we should instead maintain the approach that would use the 2017, 2018, and 2019 benefit years' data to recalibrate the risk adjustment models for the 2022 benefit year.

The draft coefficients listed below in Tables 1 through 6 reflect the use of 2016, 2017, and 2018 benefit year enrollee-level EDGE data, as well as other risk adjustment model updates proposed in this proposed rule (including changes to the model specifications, changes to the enrollment duration factors and the pricing adjustment to Hepatitis C drugs). However, we note that the coefficients could change if the proposed recalibration policies, or other proposed modeling parameters, are not finalized or are modified in response to comments. In addition, consistent with § 153.320(b)(1)(i), if we are unable to finalize the final coefficients in time for the final rule, we would publish the final coefficients for the 2022 benefit year in guidance soon after the publication of the final rule.

b. Risk Adjustment Model Updates

Beginning with the 2022 benefit year, we are proposing two modeling updates to the risk adjustment models. These proposed updates include changes to the model specifications for the adult and child models and to the enrollment duration factors in the adult models to improve the models' prediction. We are also proposing to continue the market pricing adjustment for the Hepatitis C drugs that has been in place since the 2020 benefit year.

(1) Changes to the Model Specifications

Beginning with the 2022 benefit year, we are proposing to modify the adult and child models specifications to improve prediction for enrollees at both the low and highest ends of expected expenditures. The current HHS–HCC models are estimated by a weighted least squares regression.[28] The dependent variable is annualized simulated plan liability expenditures, and the weight is the person-specific sample eligibility fraction. The effective outcome is that the models predict per member per month (PMPM) expenditures.

As described in the 2021 Payment Notice, the current HHS–HCC models, which are linear models, modestly underpredict plan liability for enrollees without HCCs (enrollees with low expected expenditures) and modestly underpredict plan liability for enrollees with the highest HCC counts.[29] In the 2021 Payment Notice, we described options that we were considering to address these issues, such as adding a non-linear term or HCC counts terms to the risk adjustment models.[30] For the non-linear model option, we considered adding a coefficient-weighted sum of payment HCCs raised to a power that could be interpreted as a measure of overall disease burden. For the HCC counts model option, we considered adding eight indicator variables corresponding to 1 to 8-or-more payment HCCs, similar to the CMS–HCC risk adjustment counts models used for Medicare Advantage.[31] We have further evaluated the performance of these options, their potential for improved prediction, and considered other alternatives to improve the HHS risk adjustment models' prediction.

Our initial analyses showed that the non-linear and HCC counts models would yield considerable gains in predictive accuracy in the adult models across several groups when compared to the current linear models.[32] We tested both the count and non-linear models' impact on the adult silver risk adjustment models and found that the enrollees in the lowest cost deciles had better predictive ratios under either the HCC counts or non-linear model specification than under the current linear model specification. However, both models had shortcomings that prompted us to consider alternate model options. For the HCC counts model, we were concerned that the presence of counts across all HCCs may promote gaming in coding practices. We explored ways to assure modeling convergence across all metals and data years, and found that the non-linear models did not consistently converge in all testing scenarios, and that convergence could not reliably be assured without constraining model factors and revising those techniques with each metal and data year model run. Therefore, we continued to explore additional types of model specifications refinements that could balance the goals of improving the models' prediction with mitigating modeling complexity and gaming concerns. Specifically, as described later in this section, we explored a two-stage specification with additional weighting in the second stage based on the inverse capped prediction from the first stage (''two-stage specification''), a specification with HCC counts included for a small number of severe and transplant HCCs (''interacted HCC counts factors''), and an approach combining the two-stage specification with the interacted HCC counts factors.

For the two-stage specification, we explored calibrating the adult and child models in two stages: In the first-stage

[27] As detailed earlier, the 2022 benefit year recalibration would rely on the same 3 years of enrollee-level EDGE data that were used in the 2021 benefit year. For the 2023 benefit year and beyond, the recalibration would rely on 2 years of the enrollee-level data that were used in the prior year.

[28] See, for example, 78 FR 15420 and Section 3.7 of the ''March 31, 2016 HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper,'' March 24, 2016. Available at *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.*

[29] 85 FR 29188 and 29189.

[30] Ibid.

[31] ''Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for the Medicare Advantage (MA) CMS–HCC Risk Adjustment Model,'' December 20, 2018. Available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part1.pdf.*

[32] 85 FR 7101 through 7104.

estimation, the model coefficients would be estimated using the current model specifications; and in the second stage, we would re-estimate the model weighted by the reciprocal of the predicted values of relative expenditures from the first step estimation with the same model specification.[33] The first stage of the weighted estimation method involves a linear regression (weighted by the person-specific eligibility fraction of the number of months enrolled divided by 12) of simulated plan liability on age-sex factors, payment HCC factors, the enrollment duration factors,[34] and RXCs for the adult models. For the child models, the first stage of the weighted estimation method involves a linear regression of simulated plan liability on age-sex factors and payment HCC factors. The second stage involves using the reciprocal of first-stage predictions as weights for a second linear regression.[35] To stabilize the weights for the second stage estimation, we imposed lower and upper bound caps on the first-stage predictions at the 2.5th and 97.5th percentiles in the adult models, and the 2.5th and 99.5th percentiles in the child models. We tested various caps for the weights based on the distribution of costs, and found these lower and upper bound caps achieved better prediction on average. This approach has the material effect of weighting the healthier enrollees, who represent a majority of enrollees in the individual and small group (including merged) markets but who are underpredicted by the current models, more heavily so that the statistical model predicts their expenditures more accurately. On the other hand, this approach systematically underweights, and therefore underpredicts, very expensive enrollees. However, the capped weighting approach mitigated the potential to underpredict at the high end for expensive enrollees, as well as any possible low-end overprediction. In our consideration of this option, we tested various weights, including reciprocals of square root of prediction, log of prediction, and residuals from first step estimation, but the reciprocal of the capped predictions resulted in better predictive ratios for low-cost enrollees compared to any of these alternative weighting functions.

We also explored how the addition of severe and transplant indicators interacted with HCC counts, wherein an indicator flagging the presence of at least one severe or transplant payment HCC is being interacted with counts of the enrollee's payment HCCs.[36] The goals for this approach were to: (1) Address the non-linearity in costs between enrollees with no or very low costs and enrollees with high costs; (2) empirically incorporate the cost impact of multiple complex diseases; and (3) mitigate the gaming concerns with the HCC counts model. We tested different types of severity and transplant indicators interacted with HCC counts with the goal of improving prediction for enrollees with the highest costs and multiple HCCs to counter balance the reciprocal prediction weights that relatively underpredicted costs for these enrollees. For this approach, we assessed the HCCs for enrollees with extremely high costs, and HCCs that were being underpredicted in the current risk adjustment models. We found that many of the HCCs that were flagged as being underpredicted were those HCCs in the severe illness indicators, the transplant HCCs, and other HCCs related to severity of disease; therefore, we considered dropping the current severity illness indicators in the adult models and replacing them with severity and transplant indicators interacted with HCC counts factors in the adult and child models. Table 3 lists the HCCs that were selected for the severity and transplant indicators for the adult and child models for purposes of exploring this option. The severity and transplant indicators were then interacted with HCC counts factors, which are described below.

The purpose of adding severity and transplant indicators interacted with HCC counts factors is to account for the fact that costs of certain HCCs rise significantly when they occur with multiple other HCCs. However, in order to mitigate the incentive to upcode multiple HCCs, we only increased incremental risk scores in the presence of at least one of the selected HCCs in the severity or transplant indicator groups in Table 3. That is, an enrollee must have at least one HCC in the ''severity'' or ''transplant'' indicator groups in Table 3 to receive the interacted HCC counts coefficient toward their risk score.

Under this approach, when an enrollee has a severity indicator HCC in Table 3, the enrollee's risk score includes the sum of: (1) Severity HCC variable coefficient;[37] and (2) applicable severity HCC counts variable coefficient. The HCC counts factors, which indicate the counts of all payment HCCs for an enrollee with at least one HCC, interacted with the severity indicator in Table 3, range from one, two, to 10+ payment HCCs (1, 2, . . . , 10+) for the adult models, and from one, two, to 5, then 6 or 7, and 8+ payment HCCs for the child models. To implement the severity indicator HCC counts factors and further explore this option, we removed the current severe illness indicators in the adult models, and added severity indicator interacted HCC counts variables for the adult and child models.

For the transplant-related HCCs within the severity indicator HCC counts in Table 3,[38] we found separating out transplant HCCs into their own additional indicator to interact HCC counts factors improved prediction for these high-cost enrollees. Therefore, for the transplant HCCs, we created a separate transplant indicator to interact with payment HCC counts of 4, 5, 6, 7, or 8+ for the adult models, and a single indicator variable of payment HCC counts of 4+ for the child models. For example, an adult enrollee with a transplant HCC 34 ''Liver Transplant Status/Complications'' in the transplant indicator group and three other payment HCCs received the following factors toward their risk score in the adult models: (1) The four coefficients for their individual HCCs (the three non-transplant HCCs and the HCC 34 transplant HCC coefficient), (2) severity interacted HCC counts of 4 coefficient, and (3) transplant interacted HCC

[33] This weighted approach is similar to the weighted least squares approach with the weight equal to the reciprocal of the estimated variance that is often used to correct for heteroskedasticity. However, in our proposed approach, we would use the reciprocal of predictions from the first step as weights to correct for underprediction of low-valued coefficients.

[34] We are proposing to modify the enrollment duration factors in the adult models, as described elsewhere in this proposed rule.

[35] Under the two-stage specification and interacted HCC counts model proposal described later in this section, we are proposing to replace the severity illness indicators in the adult risk adjustment models with the interacted HCC counts.

[36] For HCCs in a group, the group is counted at most once. These groups of HCCs in the risk adjustment models are typically detailed in the Tables 6 and 7 of the HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software.

[37] This is in addition to the HCC coefficients for any other HCCs that the enrollee has, as well other risk adjustment factors that the enrollee has (such as demographic factors). If an enrollee has no severe HCCs the severe count interaction term coefficients are not applicable.

[38] We note that one transplant HCC (HCC 18 Pancreas Transplant) is not included on the list in Table 3. HCC 18 has a much lower coefficient than any of the other transplant HCCs in the adult models and was not underpredicted by the models. Therefore, we propose to exclude it from the list in Table 3 and solicit comments on the proposed treatment of HCC 18.

counts of 4 coefficient.[39] The child model operated similarly. For a child enrollee with a transplant HCC in the transplant indicator group and three other payment HCCs, the following was used to calculate the enrollee's risk score: (1) Coefficients for all four HCCs, (including the transplant HCC coefficient), (2) severity interacted HCC counts of 4 coefficient, and (3) transplant interacted HCC counts of 4 coefficient.

As an alternative, we explored interacting the HCC counts factors with each selected severity and transplant HCC, but found it was sufficient to interact the HCC counts factors with a variable indicating the presence of at least one of the selected HCCs in each group to improve prediction for enrollees with these HCCs. We also explored different combinations of HCC counts to identify the counts factors for both indicator groups in the adult and child models that provided the best balance of reasonable sample sizes and relative cost differences between each counts factor. More specifically, in the adult models, we found that starting with 4+ HCCs for the transplant interacted factors improved predictions of enrollees at the very high end in terms of risk and cost and ending at 8+ HCCs instead of 10+ HCCs addressed the small sample sizes of enrollees with a transplant and 9 or more payment HCCs. For the child models, we found having one variable for 4+ payment HCCs provided more stable estimates given the smaller sample sizes for children than those for adults.

Lastly, we tested combining these specifications into an alternative approach that incorporated both the two-stage specification and the severity and transplant indicators interacted HCC counts factors described above. We found this combined approach generally improved prediction for enrollees at both the low and highest ends of expected expenditures. Specifically, even though we found that the age-sex factors and some HCCs might have slightly worse predictive ratios under the proposed combined approach than the current linear models, we found that this combined approach improves predictive ratios in comparison to the current models in each decile of predicted plan liability. We also found that this combined approach improves R-squared in comparison to the current model and that even though the coefficients for the model factors that are most impacted by the combined approach (the age-sex factors and the severe and transplant HCCs) are changing under the 2022 benefit year models compared to the 2021 benefit year models, the average enrollee's adult risk score in the recalibration sample in the silver metal level is only increasing slightly between 2021 benefit year models to 2022 benefit year models. Therefore, we propose to modify the HHS risk adjustment model specifications for the adult and child models by combining a two-stage specification and adding interacted HCC counts factors. For the two-stage specification, we propose calibrating the adult and child models in two stages. The first stage of the weighted estimation method would involve a linear regression of simulated plan liability on age-sex factors and payment HCC factors for the adult and child models, with the addition of the enrollment duration and RXCs factors for the adult models. The second stage would use the reciprocal of prediction as weights from the first step as a second stage linear regression. To stabilize the weights from the first stage predictions, we propose lower and upper bound caps on the predictions at the 2.5th and 97.5th percentiles in the adult models and the 2.5th and 99.5th percentiles in the child models. This two-stage specification would be combined with the severity and transplant indicators from the interacted HCC counts factors. For the severity indicator group, we propose to add separate count factors for one to 10+ payment HCCs counts factors (1, 2, . . . , 10+) for the adult models and one to 5, 6 or 7, and 8+ payment HCCs (1, 2, . . . 5, 6 or 7, 8+) for the child models. The HCCs that flag the severity indicator are listed in Table 3. For the transplant HCCs, we propose to incorporate variables for 4 to 8+ payment HCCs (4, 5, 6, 7, 8+) for the adult models and one variable for 4+ payment HCCs for the child models. All variables, including the severity and transplant indicators interacted in the interacted HCC counts factors, would be included in both stages of the regressions. We propose to incorporate these model specification updates beginning with the 2022 benefit year HHS risk adjustment adult and child models. We also propose to remove the current severity illness indicators in the adult models beginning with the 2022 benefit year.

The coefficients presented in Tables 1 and 2 incorporate these proposed changes and Table 3 provides the list of severity and transplant HCCs that apply for the interacted HCC counts factors. We seek comment on these proposals, including on the HCCs selected for flagging as severity and transplant indicators listed in Table 3 such as whether we should include HCC 18 Pancreas Transplant in the transplant indicator group, and the alternatives described above. We also request comment on whether we should pursue both the interacted HCC counts factors and the two-stage specification beginning with the 2022 benefit year (as proposed), if we should implement one of the two approaches beginning with the 2022 benefit year (and if so, which one), or if we should wait to implement the proposed changes that combines the proposed model specification updates until the 2023 benefit year.

c. Changes to the Enrollment Duration Factors

In this rule, we propose changes to the enrollment duration factors in the adult risk adjustment models to improve the prediction for partial year enrollees with HCCs. As described in the proposed 2021 Payment Notice, we have been considering potential adjustments to the enrollment duration factors and previously analyzed the current factors using the 2016 and 2017 enrollee-level EDGE data.[40] We explored heterogeneity (variations) of costs for partial year enrollees in the presence of certain diagnosis codes, by market (individual or small group),[41] and under various 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 the current enrollment duration factors are driven by enrollees with HCCs. That is, partial year enrollees with HCCs had higher PMPM expenditures on average as compared to full year enrollees with HCCs. On the other hand, partial year enrollees without HCCs were not significantly different in PMPM expenditures compared to full year enrollees without HCCs. In the 2021 Payment Notice, we also explained that our preliminary analysis found that, 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. While we did not make changes to the enrollment

[39] This is in addition to other risk adjustment factors that the enrollee has (such as demographic factors).

[40] See 85 FR 7103 and 7104.

[41] In the enrollee-level EDGE data, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

duration factors in the 2021 Payment Notice, we stated that we were considering eliminating the monthly enrollment duration factors up to 11 months and replacing them with monthly enrollment duration factors up to 6 months for enrollees with HCCs. We also stated that we intended to review the trends observed in our preliminary analysis using an additional year's data before proposing changes.

Since the publication of the 2021 Payment Notice, we have reassessed enrollment duration factors for adults using the 2018 benefit year enrollee-level EDGE data. The additional data year's findings were consistent with our prior finding that partial year enrollees without HCCs do not have PMPM expenditures that are significantly different compared to full year enrollees without HCCs. We also found that the current enrollment duration factors underpredict plan liability for partial year adult enrollees with HCCs, and overpredict plan liability for partial year adult enrollees without HCCs. Therefore, beginning with the 2022 benefit year, we are proposing to remove the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, and add new monthly enrollment duration factors of up to 6 months to the adult models that would only apply for enrollees with payment HCCs. If finalized as proposed, this would mean there would be no enrollment duration factors for adult enrollees without payment HCCs starting with the 2022 benefit year adult models. As part of this analysis, we also considered adoption of enrollment duration factors by market, but we did not find a meaningful distinction in relative costs between markets on average once we implemented the proposed enrollment duration factors of up to 6 months for adult enrollees with payment HCCs. Therefore, we are not proposing enrollment duration factors for the adult models by market type at this time. We are also proposing to continue to incorporate enrollment duration factors only in the adult models.[42] We solicit comment on the proposed changes to the enrollment duration factors for the adult models. We also seek comment on whether we should implement these model changes starting with the 2022 benefit year, whether we should delay implementation until the 2023 benefit year, or whether we should create the enrollment duration factors for different lengths, such as up to 9 months of enrollment, instead of up to 6 months, as proposed.

d. Pricing Adjustment for the Hepatitis C Drugs

For the 2022 benefit year models, we propose to continue applying the market pricing adjustment to the plan liability associated with Hepatitis C drugs that has been in place beginning with the 2020 benefit year final risk adjustment models.[43] We continue to believe this market pricing adjustment is necessary to account for the significant pricing changes associated with the introduction of new and generic Hepatitis C drugs between the data years used for recalibrating the models and the applicable recalibration 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 that is higher than the actual plan liability of the drug claim, and therefore, make the risk adjustment transfer results more favorable for the issuer. We previously stated that we intended to reassess this pricing adjustment with future benefit years' enrollee-level EDGE data.[44] We remain committed to doing so. However, we are proposing to use the same 3 years of enrollee-level EDGE data for the 2022 benefit year model recalibration as those used for the 2021 benefit year. Therefore, we propose to continue making the market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the 2022 benefit year models.[45] We intend to reassess this pricing adjustment in future recalibrations with additional years of enrollee-level EDGE data. We seek comment on this proposal.

e. List of Factors To Be Employed in the Risk Adjustment Models (§ 153.320)

The proposed 2022 benefit year risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2016, 2017, and 2018 enrollee-level EDGE data, including all of the proposed model changes detailed above, are shown in Tables 1 through 6. The adult, child, and infant models have been truncated to account for the high-cost risk pool payment parameters by removing 60 percent of costs above the $1 million threshold.[46] Table 1 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC–HCC interactions, interacted HCC counts, and enrollment duration coefficients. Table 2 contains the factors for each child model. Table 3 lists the HHS–HCCs in the proposed severity and transplant indicator flags selected for the interacted HCC counts factors that would apply to the adult and child models beginning with the 2022 benefit year. Table 4 contains the factors for each infant model. Tables 5 and 6 contain the HCCs included in the infant models' maturity and severity categories, respectively.

TABLE 1—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2022 BENEFIT YEAR

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Demographic Factors					
	Age 21–24, Male	0.179	0.134	0.098	0.070	0.068
	Age 25–29, Male	0.184	0.138	0.102	0.074	0.073
	Age 30–34, Male	0.214	0.162	0.120	0.087	0.085
	Age 35–39, Male	0.248	0.188	0.140	0.100	0.097
	Age 40–44, Male	0.277	0.213	0.159	0.114	0.111
	Age 45–49, Male	0.310	0.240	0.182	0.131	0.128
	Age 50–54, Male	0.393	0.316	0.249	0.191	0.188

[42] As explained in the 2021 Payment Notice proposed rule, 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 they tended to have similar risk to full year enrollees in the child models. In the infant models, we found that partial year infants had higher expenditures on average compared to their full year counterparts; however, the incorporation of enrollment duration factors created interaction issues with the current severity and maturity factors and did not have a meaningful impact on the general predictive accuracy of the infant models. See 85 FR 7103 and 7104.

[43] 84 FR 17463 through 17466.

[44] 85 FR 29185.

[45] The Hepatitis C drugs market pricing adjustment to plan liability is applied for all enrollees taking Hepatitis C drugs in the data used for recalibration.

[46] As detailed below, we are not proposing changes to the high-cost risk pool parameters for the 2022 benefit year. Therefore, as proposed, we would maintain the $1 million threshold and 60 percent coinsurance rate.

TABLE 1—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2022 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
	Age 55–59, Male	0.446	0.359	0.285	0.221	0.217
	Age 60–64, Male	0.524	0.427	0.343	0.270	0.265
	Age 21–24, Female	0.292	0.223	0.167	0.125	0.123
	Age 25–29, Female	0.319	0.244	0.183	0.138	0.136
	Age 30–34, Female	0.375	0.290	0.221	0.165	0.162
	Age 35–39, Female	0.428	0.336	0.258	0.194	0.190
	Age 40–44, Female	0.484	0.383	0.297	0.223	0.218
	Age 45–49, Female	0.507	0.401	0.309	0.229	0.225
	Age 50–54, Female	0.565	0.459	0.364	0.281	0.276
	Age 55–59, Female	0.569	0.461	0.366	0.283	0.278
	Age 60–64, Female	0.616	0.505	0.405	0.320	0.315
	Diagnosis Factors					
HCC001	HIV/AIDS	1.372	1.241	1.148	1.066	1.062
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.	9.748	9.526	9.394	9.265	9.261
HCC003	Central Nervous System Infections, Except Viral Meningitis.	8.571	8.427	8.323	8.202	8.195
HCC004	Viral or Unspecified Meningitis	8.571	8.427	8.323	8.202	8.195
HCC006	Opportunistic Infections	8.171	8.081	7.987	7.849	7.840
HCC008	Metastatic Cancer	24.079	23.695	23.536	23.460	23.461
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	14.384	14.117	13.991	13.897	13.896
HCC010	Non-Hodgkin Lymphomas and Other Cancers and Tumors.	5.887	5.722	5.626	5.532	5.528
HCC011	Colorectal, Breast (Age <50), Kidney, and Other Cancers.	3.865	3.677	3.547	3.410	3.404
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.	2.559	2.414	2.305	2.185	2.180
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.	1.134	1.018	0.893	0.744	0.735
HCC018	Pancreas Transplant Status	0.875	0.813	0.806	1.044	1.021
HCC019	Diabetes with Acute Complications	0.385	0.323	0.262	0.202	0.198
HCC020	Diabetes with Chronic Complications	0.385	0.323	0.262	0.202	0.198
HCC021	Diabetes without Complication	0.385	0.323	0.262	0.202	0.198
HCC022	Type 1 Diabetes Mellitus, add-on to Diabetes HCCs 19–21.	0.311	0.276	0.242	0.173	0.169
HCC023	Protein-Calorie Malnutrition	10.875	10.752	10.670	10.587	10.582
HCC026	Mucopolysaccharidosis	28.668	28.458	28.362	28.308	28.309
HCC027	Lipidoses and Glycogenosis	28.668	28.458	28.362	28.308	28.309
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders.	7.531	7.405	7.319	7.244	7.242
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders.	1.328	1.224	1.125	1.007	1.001
HCC034	Liver Transplant Status/Complications	8.038	7.973	7.884	7.864	7.853
HCC035_1 [47]	Acute Liver Failure/Disease, Including Neonatal Hepatitis.	7.063	6.914	6.849	6.800	6.798
HCC035_2	Chronic Liver Failure/End-Stage Liver Disorders	2.906	2.734	2.630	2.520	2.516
HCC036	Cirrhosis of Liver	1.283	1.180	1.078	0.946	0.938
HCC037_1	Chronic Viral Hepatitis C	0.830	0.731	0.637	0.529	0.523
HCC037_2	Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.830	0.731	0.637	0.529	0.523
HCC041	Intestine Transplant Status/Complications	23.291	23.157	23.033	22.817	22.812
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.	11.657	11.449	11.339	11.253	11.250
HCC045	Intestinal Obstruction	4.859	4.672	4.585	4.484	4.482
HCC046	Chronic Pancreatitis	3.262	3.088	3.000	2.913	2.912
HCC047	Acute Pancreatitis	2.933	2.727	2.593	2.418	2.412
HCC048	Inflammatory Bowel Disease	0.820	0.731	0.626	0.488	0.479
HCC054	Necrotizing Fasciitis	8.872	8.708	8.632	8.596	8.595
HCC055	Bone/Joint/Muscle Infections/Necrosis	4.708	4.536	4.467	4.432	4.432
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders.	1.340	1.230	1.121	1.001	0.994
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders.	0.878	0.782	0.664	0.514	0.505
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies.	2.463	2.304	2.185	2.051	2.044
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders.	2.463	2.304	2.185	2.051	2.044
HCC063	Cleft Lip/Cleft Palate	1.676	1.544	1.437	1.309	1.303
HCC066	Hemophilia	69.981	69.651	69.503	69.435	69.435
HCC067	Myelodysplastic Syndromes and Myelofibrosis	13.285	13.162	13.096	13.039	13.036
HCC068	Aplastic Anemia	13.285	13.162	13.096	13.039	13.036
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.	13.285	13.162	13.096	13.039	13.036
HCC070	Sickle Cell Anemia (Hb-SS)	2.395	2.283	2.191	2.082	2.077
HCC071	Beta Thalassemia Major	2.395	2.283	2.191	2.082	2.077
HCC073	Combined and Other Severe Immunodeficiencies	4.039	3.936	3.888	3.840	3.839
HCC074	Disorders of the Immune Mechanism	4.039	3.936	3.888	3.840	3.839
HCC075	Coagulation Defects and Other Specified Hematological Disorders.	1.763	1.672	1.594	1.499	1.495

TABLE 1—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2022 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC081	Drug Use with Psychotic Complications	2.438	2.264	2.108	1.897	1.885
HCC082	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications.	2.438	2.264	2.108	1.897	1.885
HCC083	Alcohol Use with Psychotic Complications	1.296	1.171	1.057	0.911	0.903
HCC084	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications.	1.296	1.171	1.057	0.911	0.903
HCC087_1	Schizophrenia	2.445	2.260	2.121	1.961	1.954
HCC087_2	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis.	2.372	2.199	2.067	1.894	1.886
HCC088	Major Depressive Disorder, Severe, and Bipolar Disorders.	1.271	1.141	1.008	0.838	0.829
HCC090	Personality Disorders	0.856	0.742	0.606	0.446	0.435
HCC094	Anorexia/Bulimia Nervosa	2.223	2.099	1.993	1.875	1.869
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.	8.930	8.904	8.869	8.785	8.778
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.	1.051	0.965	0.880	0.783	0.777
HCC102	Autistic Disorder	0.974	0.865	0.741	0.602	0.593
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder.	0.856	0.742	0.606	0.446	0.435
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	10.321	10.159	10.050	9.940	9.936
HCC107	Quadriplegia	10.321	10.159	10.050	9.940	9.936
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	7.300	7.190	7.148	7.079	7.076
HCC109	Paraplegia	7.300	7.190	7.148	7.079	7.076
HCC110	Spinal Cord Disorders/Injuries	5.109	4.928	4.832	4.737	4.734
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.	3.983	3.791	3.637	3.454	3.445
HCC112	Quadriplegic Cerebral Palsy	2.457	2.306	2.196	2.073	2.070
HCC113	Cerebral Palsy, Except Quadriplegic	0.911	0.825	0.739	0.628	0.621
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.	1.633	1.516	1.406	1.273	1.266
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	5.117	5.042	5.019	4.999	4.999
HCC117	Muscular Dystrophy	1.717	1.593	1.473	1.307	1.298
HCC118	Multiple Sclerosis	3.304	3.144	3.019	2.877	2.870
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.	1.717	1.593	1.473	1.307	1.298
HCC120	Seizure Disorders and Convulsions	1.262	1.142	1.028	0.887	0.879
HCC121	Hydrocephalus	10.147	10.050	9.987	9.914	9.910
HCC122	Coma, Brain Compression/Anoxic Damage	10.005	9.852	9.745	9.624	9.618
HCC123	Narcolepsy and Cataplexy	5.856	5.690	5.554	5.405	5.397
HCC125	Respirator Dependence/Tracheostomy Status	21.425	21.213	21.080	20.954	20.949
HCC126	Respiratory Arrest	8.941	8.754	8.635	8.523	8.520
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.	8.941	8.754	8.635	8.523	8.520
HCC128	Heart Assistive Device/Artificial Heart	21.035	20.838	20.709	20.586	20.580
HCC129	Heart Transplant Status/Complications	21.035	20.838	20.709	20.586	20.580
HCC130	Heart Failure	2.046	1.947	1.874	1.792	1.788
HCC131	Acute Myocardial Infarction	6.142	5.902	5.813	5.777	5.781
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease.	4.704	4.470	4.361	4.250	4.250
HCC135	Heart Infection/Inflammation, Except Rheumatic	8.866	8.749	8.645	8.507	8.499
HCC137	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.	1.910	1.809	1.715	1.613	1.608
HCC138	Major Congenital Heart/Circulatory Disorders	1.910	1.809	1.715	1.613	1.608
HCC139	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.	1.910	1.809	1.715	1.613	1.608
HCC142	Specified Heart Arrhythmias	1.838	1.717	1.608	1.473	1.469
HCC145	Intracranial Hemorrhage	11.065	10.884	10.774	10.662	10.658
HCC146	Ischemic or Unspecified Stroke	1.590	1.463	1.368	1.236	1.231
HCC149	Cerebral Aneurysm and Arteriovenous Malformation.	2.570	2.429	2.321	2.184	2.178
HCC150	Hemiplegia/Hemiparesis	3.409	3.301	3.271	3.263	3.266
HCC151	Monoplegia, Other Paralytic Syndromes	2.405	2.286	2.199	2.086	2.081
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene.	7.875	7.759	7.732	7.746	7.750
HCC154	Vascular Disease with Complications	5.620	5.504	5.463	5.427	5.427
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	7.977	7.859	7.751	7.617	7.608
HCC158	Lung Transplant Status/Complications	12.435	12.247	12.124	12.008	11.999
HCC159	Cystic Fibrosis	5.177	5.040	4.976	4.910	4.908
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.	0.824	0.726	0.617	0.488	0.481
HCC161_1	Severe Asthma	0.824	0.726	0.617	0.488	0.481
HCC161_2	Asthma, Except Severe	0.824	0.726	0.617	0.488	0.481
HCC162	Fibrosis of Lung and Other Lung Disorders	1.742	1.631	1.532	1.403	1.396
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	7.455	7.417	7.378	7.350	7.349

TABLE 1—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2022 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC174	Exudative Macular Degeneration	1.438	1.298	1.167	0.991	0.982
HCC183	Kidney Transplant Status/Complications	8.681	8.609	8.503	8.269	8.263
HCC184	End Stage Renal Disease	22.696	22.390	22.310	22.358	22.400
HCC187	Chronic Kidney Disease, Stage 5	0.863	0.794	0.736	0.668	0.665
HCC188	Chronic Kidney Disease, Severe (Stage 4)	0.863	0.794	0.736	0.668	0.665
HCC203	Ectopic and Molar Pregnancy	2.155	1.952	1.753	1.433	1.416
HCC204	Miscarriage with Complications	0.924	0.813	0.657	0.430	0.413
HCC205	Miscarriage with No or Minor Complications	0.924	0.813	0.657	0.430	0.413
HCC207	Pregnancy with Delivery with Major Complications	4.064	3.783	3.551	3.135	3.118
HCC208	Pregnancy with Delivery with Complications	4.064	3.783	3.551	3.135	3.118
HCC209	Pregnancy with Delivery with No or Minor Complications.	2.847	2.639	2.414	1.955	1.928
HCC210	(Ongoing) Pregnancy without Delivery with Major Complications.	1.280	1.141	0.959	0.726	0.711
HCC211	(Ongoing) Pregnancy without Delivery with Complications.	0.879	0.766	0.607	0.438	0.427
HCC212	(Ongoing) Pregnancy without Delivery with No or Minor Complications.	0.352	0.280	0.190	0.123	0.119
HCC217	Chronic Ulcer of Skin, Except Pressure	1.533	1.420	1.330	1.220	1.215
HCC218	Extensive Third Degree Burns	23.966	23.738	23.617	23.538	23.536
HCC219	Major Skin Burn or Condition	2.364	2.241	2.145	2.041	2.036
HCC223	Severe Head Injury	17.030	16.895	16.771	16.632	16.624
HCC226	Hip and Pelvic Fractures	8.337	8.132	8.048	7.995	7.996
HCC228	Vertebral Fractures without Spinal Cord Injury	4.358	4.194	4.090	3.962	3.956
HCC234	Traumatic Amputations and Amputation Complications.	4.952	4.795	4.736	4.696	4.697
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications.	22.648	22.602	22.510	22.387	22.377
HCC253	Artificial Openings for Feeding or Elimination	6.513	6.413	6.376	6.352	6.352
HCC254	Amputation Status, Upper Limb or Lower Limb	1.806	1.671	1.574	1.456	1.451
Interacted HCC Counts Factors						
	Severe illness, 1 payment HCC	−6.091	−6.125	−6.181	−6.267	−6.271
	Severe illness, 2 payment HCCs	−5.758	−5.804	−5.824	−5.883	−5.886
	Severe illness, 3 payment HCCs	−4.600	−4.607	−4.526	−4.404	−4.393
	Severe illness, 4 payment HCCs	−3.648	−3.586	−3.415	−3.138	−3.118
	Severe illness, 5 payment HCCs	−2.965	−2.815	−2.554	−2.137	−2.110
	Severe illness, 6 payment HCCs	−2.718	−2.456	−2.103	−1.561	−1.528
	Severe illness, 7 payment HCCs	−1.848	−1.445	−0.987	−0.319	−0.281
	Severe illness, 8 payment HCCs	−1.328	−0.842	−0.328	0.405	0.446
	Severe illness, 9 payment HCCs	0.191	0.836	1.458	2.310	2.355
	Severe illness, 10 or more payment HCCs	8.579	9.578	10.431	11.526	11.579
	Transplant severe illness, 4 payment HCCs	3.559	3.502	3.483	3.483	3.487
	Transplant severe illness, 5 payment HCCs	7.420	7.365	7.353	7.363	7.368
	Transplant severe illness, 6 payment HCCs	12.674	12.625	12.622	12.645	12.652
	Transplant severe illness, 7 payment HCCs	18.766	18.696	18.688	18.707	18.715
	Transplant severe illness, 8 or more payment HCCs.	33.796	33.788	33.829	33.905	33.916
Enrollment Duration Factors						
	Enrolled for 1 month, at least one payment HCC	9.287	7.981	6.876	5.547	5.462
	Enrolled for 2 months, at least one payment HCC	3.618	2.896	2.336	1.799	1.768
	Enrolled for 3 months, at least one payment HCC	2.088	1.641	1.282	0.965	0.947
	Enrolled for 4 months, at least one payment HCC	1.105	0.816	0.572	0.376	0.366
	Enrolled for 5 months, at least one payment HCC	0.770	0.563	0.380	0.235	0.226
	Enrolled for 6 months, at least one payment HCC	0.499	0.351	0.215	0.123	0.120
Prescription Drug Factors						
RXC 01	Anti-HIV Agents	8.499	7.914	7.511	7.007	6.990
RXC 02	Anti-Hepatitis C (HCV) Agents, Direct Acting Agents.	6.593	6.146	5.958	5.830	5.835
RXC 03	Antiarrhythmics	0.117	0.107	0.103	0.069	0.050
RXC 04	Phosphate Binders	2.009	2.016	2.007	1.953	1.880
RXC 05	Inflammatory Bowel Disease Agents	1.519	1.374	1.206	0.941	0.924
RXC 06	Insulin	1.227	1.005	0.762	0.500	0.483
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only.	0.671	0.570	0.463	0.346	0.339
RXC 08	Multiple Sclerosis Agents	23.184	22.318	21.874	21.467	21.466
RXC 09	Immune Suppressants and Immunomodulators	12.774	12.347	12.139	11.992	11.988
RXC 10	Cystic Fibrosis Agents	17.803	17.474	17.358	17.299	17.304
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 and HCC 001.	2.316	2.503	2.790	3.284	3.310
RXC 02 x HCC 37_1, 36_035_s_34.	Additional effect for enrollees with RXC 02 and (HCC 037_1 or 036 or 035_2 or 035_1 or 034).	−0.678	−0.555	−0.433	−0.264	−0.256
RXC_03_x_HCC142	Additional effect for enrollees with RXC 03 and HCC 142.	0.000	0.000	0.000	0.000	0.000
RXC_04_x_HCC184_183_187_188.	Additional effect for enrollees with RXC 04 and (HCC 184 or 183 or 187 or 188).	0.000	0.000	0.000	0.000	0.000

TABLE 1—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2022 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC_05_x_HCC048_041	Additional effect for enrollees with RXC 05 and (HCC 048 or 041).	−0.381	−0.341	−0.282	−0.235	−0.231
RXC_06_x_HCC018_019_020_021.	Additional effect for enrollees with RXC 06 and (HCC 018 or 019 or 020 or 021).	0.560	0.647	0.761	0.781	0.784
RXC_07_x_HCC018_019_020_021.	Additional effect for enrollees with RXC 07 and (HCC 018 or 019 or 020 or 021).	−0.204	−0.151	−0.117	−0.134	−0.136
RXC_08_x_HCC118	Additional effect for enrollees with RXC 08 and HCC 118.	−0.539	−0.056	0.316	0.813	0.827
RXC_09_x_HCC056_057_and_048_041.	Additional effect for enrollees with RXC 09 and (HCC 048 or 041) and (HCC 056 or 057).	0.693	0.764	0.827	0.909	0.915
RXC_09_x_HCC056	Additional effect for enrollees with RXC 09 and HCC 056.	0.757	0.824	0.959	1.153	1.166
RXC_09_x_HCC057	Additional effect for enrollees with RXC 09 and HCC 057.	−0.878	−0.782	−0.664	−0.514	−0.505
RXC_09_x_HCC048_041	Additional effect for enrollees with RXC 09 and (HCC 048 or 041).	3.331	3.335	3.439	3.648	3.664
RXC_10_x_HCC159_158	Additional effect for enrollees with RXC 10 and (HCC 159 or 158).	46.175	46.175	46.180	46.278	46.282

TABLE 2—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2022 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.267	0.201	0.153	0.116	0.113
Age 5–9, Male	0.192	0.135	0.097	0.070	0.068
Age 10–14, Male	0.223	0.164	0.120	0.093	0.091
Age 15–20, Male	0.271	0.208	0.156	0.117	0.115
Age 2–4, Female	0.221	0.163	0.126	0.100	0.098
Age 5–9, Female	0.163	0.112	0.080	0.060	0.058
Age 10–14, Female	0.212	0.155	0.116	0.091	0.089
Age 15–20, Female	0.336	0.258	0.195	0.147	0.144
Diagnosis Factors					
HIV/AIDS	5.961	5.577	5.357	5.139	5.133
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	16.453	16.237	16.111	15.962	15.955
Central Nervous System Infections, Except Viral Meningitis	14.787	14.627	14.548	14.496	14.493
Viral or Unspecified Meningitis	12.890	12.778	12.672	12.532	12.528
Opportunistic Infections	18.089	18.031	17.967	17.889	17.881
Metastatic Cancer	33.956	33.679	33.535	33.432	33.430
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	9.363	9.131	8.985	8.839	8.833
Non-Hodgkin Lymphomas and Other Cancers and Tumors	7.171	6.961	6.817	6.657	6.649
Colorectal, Breast (Age <50), Kidney, and Other Cancers	3.764	3.582	3.413	3.207	3.192
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.764	3.582	3.413	3.207	3.192
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.098	0.968	0.841	0.678	0.675
Pancreas Transplant Status	14.723	14.594	14.579	14.489	14.535
Diabetes with Acute Complications	2.527	2.261	2.012	1.649	1.685
Diabetes with Chronic Complications	2.527	2.261	2.012	1.649	1.685
Diabetes without Complication	2.527	2.261	2.012	1.649	1.685
Protein-Calorie Malnutrition	18.838	18.721	18.666	18.639	18.634
Mucopolysaccharidosis	39.199	38.932	38.800	38.702	38.699
Lipidoses and Glycogenosis	39.199	38.932	38.800	38.702	38.699
Congenital Metabolic Disorders, Not Elsewhere Classified	5.406	5.282	5.186	5.086	5.081
Amyloidosis, Porphyria, and Other Metabolic Disorders	5.406	5.282	5.186	5.086	5.081
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.355	6.124	5.993	5.896	5.892
Liver Transplant Status/Complications	14.723	14.594	14.579	14.489	14.535
Acute Liver Failure/Disease, Including Neonatal Hepatitis	11.829	11.676	11.608	11.560	11.558
Chronic Liver Failure/End-Stage Liver Disorders	11.044	10.886	10.801	10.710	10.707
Cirrhosis of Liver	3.402	3.311	3.228	3.084	3.080
Chronic Viral Hepatitis C	2.086	1.923	1.815	1.753	1.754

[47] HCC numbers that appear with an underscore in this document will appear without the underscore in the DIY software. For example, HCC 35_1 in this table will appear as HCC 351 in the DIY software.

TABLE 2—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2022 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Chronic Hepatitis, Except Chronic Viral Hepatitis C	0.755	0.637	0.542	0.431	0.422
Intestine Transplant Status/Complications	16.105	16.018	15.984	15.983	15.990
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	18.426	18.175	18.075	18.044	18.045
Intestinal Obstruction	3.900	3.703	3.548	3.358	3.348
Chronic Pancreatitis	10.399	10.199	10.109	10.054	10.048
Acute Pancreatitis	5.156	4.921	4.757	4.537	4.524
Inflammatory Bowel Disease	9.409	9.061	8.862	8.668	8.661
Necrotizing Fasciitis	3.086	2.881	2.730	2.580	2.572
Bone/Joint/Muscle Infections/Necrosis	3.086	2.881	2.730	2.580	2.572
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.935	4.699	4.541	4.399	4.393
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.271	1.141	1.004	0.853	0.841
Osteogenesis Imperfecta and Other Osteodystrophies	1.247	1.140	1.045	0.942	0.936
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.247	1.140	1.045	0.942	0.936
Cleft Lip/Cleft Palate	1.394	1.228	1.039	0.852	0.840
Hemophilia	71.996	71.523	71.295	71.146	71.145
Myelodysplastic Syndromes and Myelofibrosis	13.679	13.505	13.401	13.301	13.296
Aplastic Anemia	13.679	13.505	13.401	13.301	13.296
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	13.679	13.505	13.401	13.301	13.296
Sickle Cell Anemia (Hb-SS)	5.557	5.356	5.213	5.061	5.056
Beta Thalassemia Major	5.557	5.356	5.213	5.061	5.056
Combined and Other Severe Immunodeficiencies	4.311	4.157	4.042	3.914	3.904
Disorders of the Immune Mechanism	4.311	4.157	4.042	3.914	3.904
Coagulation Defects and Other Specified Hematological Disorders	3.342	3.212	3.096	2.963	2.955
Drug Use with Psychotic Complications	2.473	2.289	2.136	1.945	1.934
Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications	2.473	2.289	2.136	1.945	1.934
Alcohol Use with Psychotic Complications	1.387	1.245	1.107	0.925	0.913
Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications	1.387	1.245	1.107	0.925	0.913
Schizophrenia	4.545	4.264	4.068	3.841	3.830
Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis	3.056	2.824	2.627	2.376	2.362
Major Depressive Disorder, Severe, and Bipolar Disorders	2.587	2.379	2.188	1.947	1.935
Personality Disorders	0.612	0.515	0.397	0.272	0.265
Anorexia/Bulimia Nervosa	2.511	2.348	2.211	2.071	2.063
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	12.839	12.760	12.707	12.664	12.658
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.547	1.401	1.266	1.082	1.063
Autistic Disorder	2.587	2.379	2.188	1.947	1.935
Pervasive Developmental Disorders, Except Autistic Disorder	0.612	0.515	0.404	0.304	0.299
Traumatic Complete Lesion Cervical Spinal Cord	9.556	9.348	9.228	9.121	9.119
Quadriplegia	9.556	9.348	9.228	9.121	9.119
Traumatic Complete Lesion Dorsal Spinal Cord	8.665	8.452	8.339	8.216	8.212
Paraplegia	8.665	8.452	8.339	8.216	8.212
Spinal Cord Disorders/Injuries	3.428	3.241	3.094	2.912	2.898
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	32.864	32.642	32.500	32.372	32.367
Quadriplegic Cerebral Palsy	3.270	3.108	3.041	3.010	3.014
Cerebral Palsy, Except Quadriplegic	1.319	1.156	1.018	0.836	0.823
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.890	1.769	1.676	1.566	1.559
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	9.947	9.789	9.713	9.665	9.664
Muscular Dystrophy	4.361	4.165	3.981	3.767	3.751
Multiple Sclerosis	12.642	12.278	12.119	12.017	12.015
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	4.361	4.165	3.981	3.767	3.751
Seizure Disorders and Convulsions	1.619	1.477	1.313	1.130	1.119
Hydrocephalus	12.782	12.747	12.714	12.712	12.717
Coma, Brain Compression/Anoxic Damage	12.827	12.750	12.666	12.598	12.595
Narcolepsy and Cataplexy	5.101	4.922	4.761	4.563	4.549
Respirator Dependence/Tracheostomy Status	30.364	30.125	30.016	29.935	29.930
Respiratory Arrest	15.552	15.311	15.186	15.055	15.047
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	15.552	15.311	15.186	15.055	15.047

TABLE 2—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2022 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Heart Assistive Device/Artificial Heart	16.105	16.018	15.984	15.983	15.990
Heart Transplant Status/Complications	16.105	16.018	15.984	15.983	15.990
Heart Failure	4.636	4.513	4.419	4.297	4.290
Acute Myocardial Infarction	1.745	1.578	1.435	1.332	1.336
Unstable Angina and Other Acute Ischemic Heart Disease	1.745	1.578	1.435	1.332	1.336
Heart Infection/Inflammation, Except Rheumatic	15.639	15.486	15.366	15.212	15.200
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	3.058	2.842	2.650	2.438	2.418
Major Congenital Heart/Circulatory Disorders	0.999	0.865	0.721	0.605	0.596
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	0.747	0.646	0.546	0.467	0.461
Specified Heart Arrhythmias	2.745	2.562	2.384	2.227	2.217
Intracranial Hemorrhage	14.578	14.462	14.366	14.264	14.261
Ischemic or Unspecified Stroke	1.440	1.361	1.277	1.198	1.197
Cerebral Aneurysm and Arteriovenous Malformation	2.668	2.517	2.365	2.101	2.085
Hemiplegia/Hemiparesis	4.576	4.442	4.359	4.245	4.236
Monoplegia, Other Paralytic Syndromes	3.018	2.871	2.758	2.618	2.610
Atherosclerosis of the Extremities with Ulceration or Gangrene	11.183	10.985	10.861	10.737	10.734
Vascular Disease with Complications	6.308	6.163	6.068	5.980	5.976
Pulmonary Embolism and Deep Vein Thrombosis	20.304	20.162	20.087	20.027	20.021
Lung Transplant Status/Complications	16.105	16.018	15.984	15.983	15.990
Cystic Fibrosis	48.367	47.908	47.701	47.590	47.584
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	2.003	1.844	1.699	1.518	1.508
Severe Asthma	1.185	1.018	0.827	0.633	0.622
Asthma, Except Severe	0.382	0.297	0.203	0.123	0.119
Fibrosis of Lung and Other Lung Disorders	1.185	1.018	0.827	0.633	0.622
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	12.351	12.306	12.275	12.298	12.298
Kidney Transplant Status/Complications	14.723	14.594	14.579	14.489	14.535
End Stage Renal Disease	37.215	37.008	36.936	36.933	36.936
Chronic Kidney Disease, Stage 5	3.859	3.728	3.618	3.482	3.475
Chronic Kidney Disease, Severe (Stage 4)	3.859	3.728	3.618	3.482	3.475
Ectopic and Molar Pregnancy	2.067	1.842	1.626	1.295	1.279
Miscarriage with Complications	0.912	0.778	0.597	0.346	0.329
Miscarriage with No or Minor Complications	0.912	0.778	0.597	0.346	0.329
Pregnancy with Delivery with Major Complications	3.751	3.463	3.195	2.691	2.661
Pregnancy with Delivery with Complications	3.751	3.463	3.195	2.691	2.661
Pregnancy with Delivery with No or Minor Complications	2.650	2.428	2.165	1.661	1.624
(Ongoing) Pregnancy without Delivery with Major Complications	0.977	0.822	0.619	0.388	0.374
(Ongoing) Pregnancy without Delivery with Complications	0.977	0.822	0.619	0.388	0.374
(Ongoing) Pregnancy without Delivery with No or Minor Complications	0.485	0.378	0.252	0.147	0.142
Chronic Ulcer of Skin, Except Pressure	1.504	1.383	1.263	1.141	1.135
Extensive Third Degree Burns	20.205	19.995	19.885	19.821	19.818
Major Skin Burn or Condition	1.867	1.723	1.600	1.455	1.447
Severe Head Injury	20.205	19.995	19.885	19.821	19.818
Hip and Pelvic Fractures	3.665	3.439	3.263	3.101	3.095
Vertebral Fractures without Spinal Cord Injury	3.353	3.148	2.963	2.739	2.726
Traumatic Amputations and Amputation Complications	3.936	3.723	3.565	3.352	3.338
Stem Cell, Including Bone Marrow, Transplant Status/Complications	16.105	16.018	15.984	15.983	15.990
Artificial Openings for Feeding or Elimination	7.197	7.036	6.985	6.947	6.949
Amputation Status, Upper Limb or Lower Limb	3.936	3.723	3.565	3.352	3.338
Interacted HCC Counts Factors					
Severe illness, 1 payment HCC	−11.292	−11.358	−11.441	−11.583	−11.595
Severe illness, 2 payment HCCs	−11.146	−11.138	−11.169	−11.269	−11.257
Severe illness, 3 payment HCCs	−9.366	−9.392	−9.391	−9.345	−9.341
Severe illness, 4 payment HCCs	−8.988	−8.982	−8.891	−8.710	−8.694
Severe illness, 5 payment HCCs	−7.182	−7.013	−6.744	−6.377	−6.349
Severe illness, 6 or 7 payment HCCs	−1.583	−1.238	−0.827	−0.285	−0.249
Severe illness, 8 or more payment HCCs	18.271	19.100	19.861	20.772	20.830
Transplant severe illness, 4 or more payment HCCs	17.085	17.121	17.096	17.068	17.040

TABLE 3—HCCS SELECTED FOR THE PROPOSED HCC INTERACTED COUNTS VARIABLES FOR THE ADULT AND CHILD MODELS BEGINNING WITH THE 2022 BENEFIT YEAR

Payment HCC	Severity illness indicator	Transplant indicator[48]
HCC 2 Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	X	
HCC 3 Central Nervous System Infections, Except Viral Meningitis	X	
HCC 4 Viral or Unspecified Meningitis	X	
HCC 6 Opportunistic Infections	X	
HCC 23 Protein-Calorie Malnutrition	X	
HCC 34 Liver Transplant Status/Complications	X	X
HCC 41 Intestine Transplant Status/Complications	X	X
HCC 42 Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	X	
HCC 96 Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	X	
HCC 121 Hydrocephalus	X	
HCC 122 Coma, Brain Compression/Anoxic Damage	X	
HCC 125 Respirator Dependence/Tracheostomy Status	X	
HCC 135 Heart Infection/Inflammation, Except Rheumatic	X	
HCC 145 Intracranial Hemorrhage	X	
HCC 156 Pulmonary Embolism and Deep Vein Thrombosis	X	
HCC 158 Lung Transplant Status/Complications	X	X
HCC 163 Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	X	
HCC 183 Kidney Transplant Status/Complications	X	X
HCC 218 Extensive Third Degree Burns	X	
HCC 223 Severe Head Injury	X	
HCC 251 Stem Cell, Including Bone Marrow, Transplant Status/Complications	X	X
G13 (Includes HCC 126 Respiratory Arrest and HCC 127 Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes)	X	
G14 (Includes HCC 128 Heart Assistive Device/Artificial Heart and HCC 129 Heart Transplant Status/Complications)	X	X

TABLE 4—PROPOSED INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2022 BENEFIT YEAR

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	228.512	227.071	226.378	225.986	225.985
Extremely Immature * Severity Level 4	143.939	142.392	141.573	140.987	140.976
Extremely Immature * Severity Level 3	32.833	31.691	31.019	30.471	30.451
Extremely Immature * Severity Level 2	32.833	31.691	31.019	30.471	30.451
Extremely Immature * Severity Level 1 (Lowest)	32.833	31.691	31.019	30.471	30.451
Immature * Severity Level 5 (Highest)	132.085	130.648	129.935	129.486	129.480
Immature * Severity Level 4	69.277	67.949	67.232	66.691	66.675
Immature * Severity Level 3	32.833	31.691	31.019	30.471	30.451
Immature * Severity Level 2	28.029	26.918	26.246	25.672	25.650
Immature * Severity Level 1 (Lowest)	25.390	24.329	23.673	23.095	23.072
Premature/Multiples * Severity Level 5 (Highest)	109.526	108.295	107.661	107.236	107.227
Premature/Multiples * Severity Level 4	28.669	27.553	26.884	26.312	26.294
Premature/Multiples * Severity Level 3	14.196	13.345	12.721	12.054	12.022
Premature/Multiples * Severity Level 2	8.093	7.463	6.897	6.212	6.173
Premature/Multiples * Severity Level 1 (Lowest)	5.774	5.254	4.759	4.243	4.214
Term * Severity Level 5 (Highest)	82.605	81.544	80.955	80.511	80.498
Term * Severity Level 4	15.976	15.156	14.564	13.941	13.916
Term * Severity Level 3	6.071	5.541	5.020	4.437	4.404
Term * Severity Level 2	3.634	3.194	2.696	2.144	2.111
Term * Severity Level 1 (Lowest)	1.853	1.534	1.163	0.917	0.905
Age 1 * Severity Level 5 (Highest)	63.472	62.803	62.434	62.174	62.167
Age 1 * Severity Level 4	12.474	12.010	11.689	11.375	11.362
Age 1 * Severity Level 3	3.139	2.867	2.637	2.419	2.408
Age 1 * Severity Level 2	1.980	1.751	1.529	1.304	1.291
Age 1 * Severity Level 1 (Lowest)	0.573	0.496	0.442	0.403	0.401
Age 0 Male	0.608	0.566	0.525	0.459	0.455
Age 1 Male	0.106	0.090	0.072	0.051	0.050

[48] We note that one transplant HCC (HCC 18 Pancreas Transplant) is not included on this list. HCC 18 had a much lower coefficient than any of the other transplant HCCs in the adult models and was not underpredicted by the models. However, we are considering whether we should add HCC 18 to the interacted HCC counts model specifications.

TABLE 5—HHS HCCs INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birth weight <500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750–999 Grams.
Immature	Premature Newborns, Including Birth weight 1000–1499 Grams.
Immature	Premature Newborns, Including Birth weight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birth weight 2000–2499 Grams.
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight.
Age 1	All age 1 infants.

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC/Description
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status.
Severity Level 5	Liver Transplant Status/Complications.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant Status/Complications.
Severity Level 5	Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status/Complications.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 4	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 4	Chronic Liver Failure/End-Stage Liver Disorders.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age <2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Combined and Other Severe Immunodeficiencies.
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers.
Severity Level 3	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.
Severity Level 3	Lipidoses and Glycogenosis.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Disorders of the Immune Mechanism.
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC/Description
Severity Level 3	Drug Use with Psychotic Complications.
Severity Level 3	Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications.
Severity Level 3	Alcohol Use with Psychotic Complications.
Severity Level 3	Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.
Severity Level 3	Extensive Third Degree Burns.
Severity Level 3	Severe Head Injury.
Severity Level 3	Hip and Pelvic Fractures.
Severity Level 3	Vertebral Fractures without Spinal Cord Injury.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Acute Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb-SS).
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Severe Asthma.
Severity Level 2	Fibrosis of Lung and Other Lung Disorders.
Severity Level 2	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 2	Major Skin Burn or Condition.
Severity Level 1 (Lowest)	Chronic Viral Hepatitis C.
Severity Level 1	Chronic Hepatitis, Except Chronic Viral Hepatitis C.
Severity Level 1	Beta Thalassemia Major.
Severity Level 1	Autistic Disorder.
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma, Except Severe.
Severity Level 1	Traumatic Amputations and Amputation Complications.
Severity Level 1	Amputation Status, Upper Limb or Lower Limb.

f. Cost-Sharing Reduction Adjustments

We propose 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 2022 benefit year, to maintain stability and certainty for issuers, we are proposing to maintain the CSR factors finalized in the 2019, 2020, and 2021 Payment Notices.[49] See Table 7.

[49] See 83 FR 16930 at 16953; 84 FR 17454 at 17478 through 17479; and 85 FR 29164 at 29190.

Consistent with the approach finalized in the 2017 Payment Notice,[50] we propose 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 seek comment on these proposals.

TABLE 7—COST-SHARING REDUCTION ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variant Recipients		
100–150% of Federal Poverty Line (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
<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

g. 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.[51] We note that the proposed model specification updates generally demonstrate improvements in R-squared as well as predictive ratios. Because we propose to blend the coefficients from separately solved models based on the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data, we are publishing the R-squared statistic for each model separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 8.

TABLE 8—R-SQUARED STATISTIC FOR PROPOSED HHS RISK ADJUSTMENT MODELS

Models	R-Squared Statistic		
	2016 Enrollee-level EDGE data	2017 Enrollee-level EDGE data	2018 Enrollee-level EDGE data
Platinum Adult	0.4488	0.4465	0.4319
Gold Adult	0.4439	0.4412	0.4265
Silver Adult	0.4406	0.4376	0.4227
Bronze Adult	0.4367	0.4335	0.4182
Catastrophic Adult	0.4364	0.4332	0.4179
Platinum Child	0.3375	0.3517	0.3535
Gold Child	0.3348	0.3488	0.3506
Silver Child	0.3325	0.3463	0.3481
Bronze Child	0.3294	0.3432	0.3449
Catastrophic Child	0.3292	0.3430	0.3447
Platinum Infant	0.3268	0.3272	0.2888
Gold Infant	0.3238	0.3242	0.2855
Silver Infant	0.3218	0.3220	0.2833
Bronze Infant	0.3195	0.3197	0.2810

[50] See 81 FR 12203 at 12228.

[51] Hileman, Geof and Spenser Steele. ''Accuracy of Claims-Based Risk Scoring Models.'' Society of Actuaries. October 2016.

TABLE 8—R-SQUARED STATISTIC FOR PROPOSED HHS RISK ADJUSTMENT MODELS—Continued

Models	R-Squared Statistic		
	2016 Enrollee-level EDGE data	2017 Enrollee-level EDGE data	2018 Enrollee-level EDGE data
Catastrophic Infant	0.3194	0.3196	0.2809

h. Calculation of Plan Average Premium and State Average Premium Requirements for Extending Future Premium Credits (§ 153.320)

On August 4, 2020, HHS adopted temporary policies of relaxed enforcement for the premium rules set forth at 45 CFR 147.102, 155.200(f)(4), 155.400(e) and (g), 155.706(b)(6)(1)(A), 156.80(d), 156.210(a), and 156.286(a)(2) through (4) to allow issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage.[52] HHS provided this flexibility with the intent of supporting continuity of coverage for individuals, families, and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID–19 PHE.

In prior rulemaking,[53] CMS finalized the calculation of plan average premium in the risk adjustment state payment transfer formula as equal to the actual premiums charged to plan enrollees, weighted by the number of months enrolled, and finalized the calculation of the state average premium as equal to the average of individual plan average premiums, weighted by each plan's share of statewide enrollment in the risk pool market, based on billable member months. In the interim final rule on COVID–19, HHS set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year. In this rule, we propose how HHS would treat temporary premium credits provided for purposes of applying the state payment transfer formula for the 2021 benefit year and beyond should HHS adopt a similar relaxed enforcement stance and permit such temporary premium credits in future benefit years during a PHE declared by the Secretary of HHS (declared PHE).[54] For states where issuers of risk adjustment covered plans provide temporary premium credits when permitted by HHS, the plan average premium and statewide average premium used in the state payment transfer formula would be calculated using issuers' adjusted premium amounts. Thus, the actual premiums billed to plan enrollees would be the amounts used in the calculations under the state payment transfer formula. This is consistent with the general approach adopted in the interim final rule on COVID–19 for temporary premium credits in the 2020 benefit year.

We further propose that HHS would use adjusted plan premiums for all enrollees to whom the issuer has actually provided premium credits as a reduction to the applicable benefit year premiums, when calculating transfers under the state payment transfer formula for the 2022 benefit year and beyond. This approach would also extend to the calculation of transfers under the state payment transfer formula in states that receive approval for a request to reduce transfers under § 153.320(d)—that is, the lower actual premiums for which plan enrollees would be responsible would be the amounts used in the calculations under the state payment transfer formula to reflect these temporary premium credits. As such, if an issuer in a state with an approved 50 percent small group market reduction request for a given benefit year chooses to provide temporary premium credits, the state average premium will decrease, and HHS would apply the 50 percent transfer reduction to the lower PMPM payment or charge transfer amount calculated under the state payment transfer formula for that state's small group market for that benefit year. As detailed further later in this preamble, we also propose that issuers providing these temporary premium credits must report the lower, actual premium amounts billed to plan enrollees to their respective EDGE servers. We believe that the applicable definitions of plan average premium and state average premium retain the meaning previously finalized by reflecting the actual monthly premium billed to enrollees. This proposal builds on lessons learned from the COVID–19 PHE and would establish a framework to recognize premium credits as a reduction in premium for purposes of the HHS-operated risk adjustment program in order to align risk adjustment charges and payments under the state payment transfer formula with flexibilities HHS may provide to issuers and states in future benefit years. This proposal would not change any other aspect of the state payment transfer formula or the method for calculating payments and charges under the HHS risk adjustment methodology (inclusive of the state payment transfer formula and high-cost risk pool parameters).

2. Overview of the HHS Risk Adjustment Methodology (§ 153.320)

We propose to continue to use the HHS state payment transfer formula that was finalized in the 2021 Payment Notice.[55] Although the proposed HHS state payment transfer formula for the 2022 benefit year is unchanged from what was finalized for the previous benefit year, we are republishing it in this proposed rule. Additionally, we are republishing 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 this proposed rule.[56] We also propose to apply this state payment transfer formula, including the administrative cost reduction, for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. If this policy is finalized as proposed, we would no longer republish these formulas in future annual HHS notice of benefit and payment parameter rules unless changes are being proposed. To align with this proposal, we propose to update § 153.320(c) to replace the current language that refers

[52] "Temporary Policy on 2020 Premium Credits Associated with the COVID–19 Public Health Emergency," August 4, 2020. *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf.*

[53] 2014 Payment Notice final rule, 78 FR 15409. Also see the 2020 Payment Notice final rule, 84 FR 17454.

[54] The Secretary of the Department of HHS may, under section 319 of the PHS Act determine that: (a) A disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

[55] 84 FR 17454 at 17480 and 17485; and 85 FR 29164 at 29191.

[56] Ibid.

to HHS specifying the applicable Federally certified risk adjustment methodology in the annual HHS notice of benefit and payment parameters for the applicable year to instead require HHS to specify the applicable Federally certified risk adjustment methodology in notice and comment rulemaking that is published in advance of the applicable benefit year.

We previously defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule.[57] In the 2014 Payment Notice, we combined those concepts into a risk adjustment state payment transfer formula.[58] 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,[59] 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.[60]

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 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 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:

$\overline{P}_S$ = 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 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 combination of metal level AV, allowable rating factor, induced demand factor, and geographic cost 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.[61] 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.

We previously defined the cost scaling factor, or the statewide average premium term, as the sum of the average premium per member month of each plan i (P_i) multiplied by plan i's share of statewide enrollment in the market risk pool (s_i). The statewide average premium will be adjusted to remove a portion of the administrative costs that do not vary with claims (14 percent) as follows:

$$\overline{P}_S = (\Sigma_i (s_i \cdot P_i)) * (1 - 0.14) = (\Sigma_i (s_i \cdot P_i)) * 0.86$$

Where:

s_i = plan i's share of statewide enrollment in the market in the risk pool;
P_i = average premium per member month of plan i.

We previously adopted a 14 percent administrative cost reduction to the statewide average premium[62] and propose maintaining it for the 2022 benefit year and beyond, unless amended through notice-and-comment rulemaking.

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,[63] 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 onward, unless amended through notice-and-comment rulemaking. We are not proposing any changes to the high-cost risk pool parameters as part of this proposed rule; therefore, we would maintain the threshold of $1 million

[57] 77 FR 17220 at 17246.

[58] 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.

[59] 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).

[60] See the 2020 Payment Notice final rule for further details on why statewide average premium is the cost-scaling factor in the state payment transfer formula. See 84 FR 17454 at 17480 through 17484.

[61] As detailed elsewhere in this proposed rule, catastrophic plans are considered part of the individual market for purposes of the national high-cost risk pool payment and charge calculations.

[62] See 84 FR 17454 at 17486.

[63] 84 FR 17466 through 17468.

and coinsurance rate of 60 percent for the 2022 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;* and
TP_i = Plan *i*'s total premium amounts.

We seek comment on the proposed HHS risk adjustment methodology for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking.

3. 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 state transfers calculated by HHS under the state payment transfer formula, which is calibrated on a national dataset, for the state's individual (catastrophic or non-catastrophic risk pools), small group, or merged markets by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's markets.[64] We finalized that any requests received would be published in the applicable benefit year's proposed HHS notice of benefit and payment parameters, and the supporting evidence provided by the state in support of its request would be made available for public comment.[65]

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 HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will only make available on the CMS website 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.[66] 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 state payment transfer amount (T_i in the state payment transfer formula above). For the 2020 and 2021 benefit years, the state of Alabama submitted a 50 percent risk adjustment transfer reduction request for its small group market and HHS approved both requests.[67]

a. Requests To Reduce Risk Adjustment Transfers for the 2022 Benefit Year

For the 2022 benefit year, HHS received a request to reduce risk adjustment state transfers for the Alabama individual and small group markets[68] by 50 percent.[69] Alabama's request states that the presence of a dominant carrier in the individual and small group markets 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 individual and small group markets for the 2022 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 seek comment on this request to reduce risk adjustment state transfers in the Alabama individual and small group markets by 50 percent for the 2022 benefit year. The request and additional documentation submitted by Alabama is posted under the ''State Flexibility Requests'' heading at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html.*

b. Multi-Year State Flexibility Requests

We propose several amendments to § 153.320(d) to allow states to request a reduction to otherwise applicable risk adjustment state transfers calculated under the HHS-operated risk adjustment methodology for up to 3 years, beginning with the 2023 benefit year. Under current policy, states seeking to reduce risk adjustment state transfers in one or more of their market risk pools must submit a request to HHS each year describing the nature of their request and providing supporting documentation. HHS then reviews the request, sets forth the request in the applicable benefit year's HHS notice of benefit and payment parameters, and approves or denies it based on the evidence and analysis provided by the state in the request and the comments received to the applicable benefit year's proposed HHS notice of benefit and payment parameters. Pursuant to § 153.320(d)(1), states must submit this request annually, and HHS publishes state requests in the applicable benefit year's proposed and final annual HHS notice of benefit and payment parameters. Stakeholders have requested that HHS allow states to request multi-year risk adjustment flexibility reductions. We have continued to consider these comments and the potential benefits that multi-year requests could provide. HHS believes that there may be potential for multi-year risk adjustment flexibility requests to promote greater predictability and stability in state markets, as issuers would be able to consider the impact of a reduction to risk adjustment state transfers for their decisions on rating and participation in a state market beyond the upcoming benefit year, and the reduction in burden to states to complete this process annually. We note, however, that a potential increase in predictability and

[64] 83 FR 16955 through 16960.

[65] 45 CFR 153.320(d)(3).

[66] See 45 CFR 153.320(d)(3).

[67] See 84 FR 17484 through 17485 and 85 FR 29193 through 29194.

[68] Alabama's individual market request is for a 50 percent reduction to risk adjustment transfers for its individual market non-catastrophic and catastrophic risk pools.

[69] Due to the COVID–19 PHE, we permitted states seeking to request a reduction in risk adjustment transfers for the 2022 benefit year an extension until September 1, 2020 to submit such request.

stability assumes that the request remains in effect for longer than 1 year.

In recognition of those comments, we propose to provide the flexibility for states to request a reduction to otherwise applicable risk adjustment state transfers calculated under the HHS-operated risk adjustment methodology's state payment transfer formula for up to 3 years beginning with the 2023 benefit year. At § 153.320, we propose to redesignate current paragraph (d)(2) as paragraph (d)(3) and create a new proposed paragraph (d)(2) to capture the ability for states to request a multi-year reduction in risk adjustment state transfers. Consistent with the existing requirements captured in § 153.320(d)(1)(i) through (iii), states making single or multi-year requests would be required to submit evidence and analysis as applicable that demonstrate the following for all years to which the request would apply: (1) State-specific factors that warrant an adjustment to more precisely account for differences in actuarial risk in the state market risk pool; (2) the percentage reductions to risk adjustment state transfers; and (3) a justification for the requested reduction in risk adjustment state transfers, or evidence demonstrating that the requested state transfer reduction would have *de minimis* impact on premiums, such that any necessary premium increase for issuers likely to receive reduced payments as a result of the requested reduction to risk adjustment state transfers would not exceed 1 percent for each year for which they are requesting a reduction to risk adjustment state transfers. This requirement for multi-year requests would be captured in new proposed § 153.320(d)(2)(i)(A). Additionally, for multi-year requests, the state would be required to confirm that it does not anticipate any significant changes to the impacted state market risk pools (for example, a material change in issuer participation in the insurance market, or significant changes in issuer market share or enrollment) for the benefit years included in its multi-year request. We propose to capture the new confirmation requirement applicable to multi-year requests at the new proposed § 153.320(d)(2)(i)(B).

As part of the new framework to permit multi-year requests, at § 153.320, we also propose to redesignate current paragraph (d)(4) as paragraph (d)(5) and to amend the reference in redesignated paragraph (d)(5)(i) to refer to redesignated paragraph (d)(5)(ii) and new proposed paragraph (d)(5)(iii). This new proposed paragraph would add language to provide HHS with authority to approve a shorter duration than that requested by the state if the supporting evidence and analysis provided by the state do not support the requested duration. This is similar to the existing authority in redesignated paragraph (d)(5)(ii) for HHS to approve a reduction amount that is lower than the amount requested by the state if the supporting evidence and analysis do not fully support the requested reduction amount. We believe this language is necessary and appropriate as it remains unclear if a state would have all of the necessary information to support a multi-year request at the time of initial application. Rather than adopt an approach that requires HHS to either approve all of the years requested by the state or none of them, the new proposed paragraph (d)(5)(iii) provides flexibility for HHS to approve the reduction for those years for which the supporting evidence and analysis support the requested reduction. We clarify that, if adopted as proposed, nothing in this new framework would prevent a state whose multi-year request was approved for a shorter duration to pursue a new, separate state flexibility request for the applicable benefit years that were not supported in the state's initial reduction request.

Recognizing that market conditions can change from one year to the next, we propose to reserve the right to require states with approved multi-year reduction requests to submit supplemental evidence in any subsequent year of the request after its initial approval, in the timeframe, form, and manner specified by HHS, when circumstances warrant. For example, after we have approved a multi-year request, if we become aware of an anticipated change in the state market risk pool to which the request applies (for example, new entrants or significant shifts in enrollment), we would ask the state to submit supplemental evidence demonstrating that it anticipates the applicable requirements regarding the impact of the reduction will still be met in the subsequent benefit years of the request. We would require the state to respond to our request for supplemental evidence within 30 calendar days of our request, and we would make such a request no later than February of the benefit year prior to the applicable benefit year (thus, we would request supplemental evidence from the state by February 2023 for the 2024 benefit year). We propose to create a new proposed § 153.320(d)(5)(iv) to capture this authority and to make a parallel amendment to add a new proposed paragraph (d)(2)(i)(C) to capture the state's obligation to respond to such requests. Codifying the ability for HHS to request that the state submit additional supplemental evidence after an initial approval of a multi-year state flexibility request is intended to address situations where a state may need to justify the continued application of the state flexibility request in the event that HHS projects a significant change in state market risk pool conditions during the term of the approved multi-year request based on review of newly available information or data.

HHS also proposes to retain the ability to terminate or modify the request during any one of the subsequent years of an approved multi-year request if additional data or new information does not support the continuation of the state's reduction request as written and the state has not provided sufficient supplemental evidence to rebut such data or information. HHS would inform the state department of insurance (DOI) of the termination or modification of its reduction request, require the state DOI to notify the impacted issuers within 15 calendar days of HHS's notice to the state, and publish information on the early termination or modification of a state's multi-year request on the CMS website [70] no later than March of the year preceding the applicable benefit year, or 30 days after receipt of information requested under new proposed § 153.320(d)(5)(iv), whichever is later. We propose to add paragraph (d)(5)(v) to capture HHS's authority to terminate or modify a previously approved multi-year request in these circumstances.

In addition, we propose to permit a state to withdraw its request before its natural expiration by notifying HHS of its requested withdrawal. A state would need to notify HHS of its intent to withdraw its request, in the form and manner specified by HHS, 60 calendar days prior to the state's deadline for rate setting for the applicable benefit year. HHS would require the state DOI to notify the impacted issuers at least 45 calendar days prior to the state's deadline for rate setting for the applicable benefit year, and would publish the information on the state's withdrawal request on the CMS website.[71] We propose to add

[70] Terminations of or modifications to state risk adjustment flexibility requests would be posted under the ''Risk Adjustment State Flexibility Requests'' heading on the CMS website at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs*.

[71] State withdrawals of risk adjustment flexibility requests would be posted under the ''Risk Adjustment State Flexibility Requests'' heading on

§ 153.320(d)(2)(ii) to capture the requirements related to a state withdrawal of its approved multi-year reduction request prior to the natural expiration of the request.

We also propose to redesignate paragraph (d)(3) as paragraph (d)(4) and amend it to reflect that, beginning for the 2023 benefit year, all multi-year reduction requests would be published in the annual HHS notice of benefit and payment parameters that corresponds to the first year of the state's request (for example, a multi-year request applicable for the 2023 through 2025 benefit years would be published in the 2023 Payment Notice proposed rule). As noted above, we propose to publish information on any early terminations or modifications by HHS or state withdrawals of approved state multi-year reduction requests on the CMS website.

We seek comment on all aspects of the proposed framework to permit states to pursue multi-year state flexibility reduction requests under § 153.320(d) for up to 3 years, including the additional components that would apply to such requests, the timeframe for states to respond to HHS requests for supplemental data and evidence pertaining to multi-year reduction requests, and the proposal to only publish and solicit comments on multi-year reduction requests in the annual HHS notice of benefit and payment parameters that corresponds to the first year in which the flexibility is being requested.

4. Audits and Compliance Reviews of Issuers of Reinsurance-Eligible Plans (§ 153.410(d)) and Audits and Compliance Reviews of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))

a. Audits and Compliance Reviews of Issuers of Reinsurance-Eligible Plans (§ 153.410(d))

HHS recently completed the 2014 benefit year audits of a sample of issuers of PPACA transitional reinsurance-eligible plans. During this process, HHS encountered significant challenges that impeded its ability to efficiently administer and complete the audits. More specifically, HHS experienced difficulties receiving requested audit data and materials in a timely fashion from some issuers, and had difficulty obtaining data from these issuers in a format that was usable by HHS. HHS is of the view that codifying additional audit requirements and parameters is an appropriate and necessary measure to ensure that 2015 and 2016 benefit year audits of PPACA transitional reinsurance-eligible plans appropriately function to protect the integrity of our programs.

We propose several amendments to § 153.410(d) to provide more clarity around the audit requirements for issuers of reinsurance-eligible plans. The proposed amendments explain the audit process, including what it means to properly comply with an audit and the consequences for failing to comply with audit requirements. We also propose to expand the oversight tools available to HHS to also provide authority for HHS to conduct compliance reviews of issuers of reinsurance-eligible plans to assess compliance with the applicable requirements of subparts E and H of part 153. These proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would only be conducted in connection with confirming reinsurance-eligible plans' compliance with the standards related to reinsurance payments in subparts E and H of part 153. A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.[72] For example, HHS may require an issuer to submit data pertaining to a specific data submission (for example, capitated claims). Unlike the compliance review authority established in § 156.715, which is limited to QHP issuers participating in FFEs, the compliance review authority we propose to codify in the amendments to § 153.410(d) would apply to all issuers of reinsurance-eligible plans. We believe this flexibility is necessary and appropriate to provide a mechanism for HHS to address situations in which a systematic error or issue is identified during the random and targeted auditing of issuers of reinsurance-eligible plans, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue, but were not selected for audit in the year in question.

Specifically, we propose to rename § 153.410(d) to ''Audits and Compliance Reviews'' in order to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate issuers of reinsurance-eligible plans' compliance with the applicable requirements in subparts E and H of part 153. We similarly propose to update the introductory language in § 153.410(d) to incorporate a reference to HHS compliance reviews and to note that we would conduct these compliance reviews consistent with the standards set forth in § 156.715.

We also propose to amend the existing introductory language in § 153.410(d) to remove the last sentence that discusses audit results and the accompanying requirements that an issuer must follow if an audit results in a finding of material weakness or significant deficiency. Additionally, as detailed further below, we propose to replace this with a new proposed framework that captures more details on the audit process and requirements for reinsurance-eligible plans. As amended, the introductory language at § 153.410(d) would reflect the authority for HHS, or its designee, to audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of subparts E and H of part 153. We also propose to move the existing introductory language in paragraph (d) requiring an issuer to ensure its relevant contractors, subcontractors, and agents cooperate with audits to a new proposed section, as detailed further below.

Also at § 153.410, we propose to add new paragraph (d)(1) to establish notice and conference requirements for these audits. The introductory language in proposed new paragraph (d)(1) reflects that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan. In proposed new paragraph (d)(1)(i), we propose to codify that all audits under this section would include an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Further, we propose to amend § 153.410(d) to add a new paragraph (d)(2) to capture the requirements issuers must meet to comply with an audit under this section. Under the proposed paragraph (d)(2)(i), we propose to capture the requirement that currently appears in the introductory text of paragraph (d) for the issuer to ensure that its relevant contractors, subcontractors, and agents cooperate with any audit or compliance review under this section and also propose to expand it to similarly require the issuer to ensure its relevant employees, downstream entities and delegated entities also cooperate with any audit or compliance review under this section. In new proposed paragraph (d)(2)(ii), we propose to require issuers to submit complete and accurate data to HHS or

the CMS website at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

[72] For further details, please see 78 FR 65100.

its designees that is necessary to complete the audit. Specifically, such data would need to support the appropriateness and accuracy of the reinsurance payments under review as part of the audit. For example, HHS may request that issuers of reinsurance-eligible plans provide enrollment and claims files, plan reference data, and associated enrollee data sufficient to show that reinsurance payments received were appropriate. HHS encountered significant challenges in the 2014 benefit year audits when some issuers submitted data in a format that was not readable by HHS or its systems. To address this issue, we propose in new paragraph (d)(2)(ii) that issuers must submit audit data in the format and manner specified by HHS no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (d)(1)(i). For example, HHS may require issuers to submit the requested audit data via Electronic File Transfer. Additionally, under proposed paragraph (d)(2)(iii), HHS proposes to require that issuers respond to any audit notices, letters, request, and inquiries, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We believe that the proposed requirements in paragraph (d)(2) are necessary and appropriate to ensure the timely completion of audits and to prevent waste that results from repeated, fruitless attempts by HHS to obtain data.

Recognizing that there may be situations that warrant an extension of the timeframes under § 153.410(d)(2)(ii) or (iii), as applicable, we propose to also add a new paragraph (d)(2)(iv) to establish a process for issuers to request an extension for good cause. To request an extension, we propose to require the issuer to submit a written request to HHS within the applicable timeframe established in paragraphs (d)(2)(ii) or (iii). The written request would have to detail the reasons for the extension request and good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS' notice granting the extension of time.

Under § 153.410(d)(3), HHS proposes that it would share its preliminary audit findings with the issuer, and further proposes that the issuer would then have 30 calendar days to respond to such findings in the format and manner specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. Additionally, we propose under paragraph (d)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. We propose in new paragraph (d)(3)(ii) that if the issuer timely responds and disputes any audit finding within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

HHS proposes to add a new paragraph § 153.410(d)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We note that the actions set forth in the final audit report could require an issuer to return reinsurance payments. We maintain the regulatory requirements related to corrective action plans for reinsurance audits that currently appear in paragraph (d) in new proposed paragraph (d)(4), which states that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

Lastly, if an issuer fails to comply with the audit requirements set forth in proposed § 153.410(d), HHS proposes in paragraph (d)(5)(i) that HHS would notify the issuer of reinsurance payments received that the issuer has not adequately substantiated, and under new proposed paragraph (d)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated if the reinsurance debt is not paid. Therefore, the continued failure to comply with the audit requirements and provide the necessary information to substantiate the payments made could result in HHS recouping up to 100 percent of the reinsurance payments made to an issuer for the applicable benefit year(s) that are the subject of the audit if the reinsurance debt is not paid.

Reinsurance payment amounts recovered by HHS as a result of an audit under § 153.410(d) would be allocated, on a pro rata basis, as further payments to the U.S. Treasury under section 1341(b)(3)(B)(iv) of the PPACA and further reimbursement of administrative expenses related to operating the reinsurance program under section 1341(b)(3)(B)(ii) of the PPACA.[73]

We seek comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes for issuers to respond to audit notices, reports, inquiries, and requests for supplemental information, and the process for issuers to request an extension to respond to such requests.

b. Audits and Compliance Reviews of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))

Although currently HHS primarily uses the HHS–RADV process to audit issuers of risk adjustment covered plans, § 153.620(c) provides HHS with the authority to conduct audits of issuers of risk adjustment-covered plans outside of the HHS–RADV process. HHS intends to begin audits of issuers of risk adjustment covered plans to ensure the proper payment of high-cost risk pool payments and confirm compliance with applicable requirements. As such, similar to the proposals related to audits and compliance reviews of issuers of reinsurance-eligible plans and learning from our experience with those 2014 benefit year audits, we propose to provide more clarity around the audit requirements for issuers of risk adjustment covered plans. These proposals seek to explain the audit process, including what it means to properly comply with an audit and the consequences for failing to comply with such requirements.

We also propose to expand the oversight tools available to HHS beyond traditional audits to also provide authority for HHS to conduct compliance reviews of risk adjustment covered plans to assess compliance with the applicable requirements of subparts

[73] See the Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, Final Rule, 79 FR 30240 at 30257 through 30259 (May 27, 2014).

G and H of part 153. These proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would only be conducted in connection with confirming risk adjustment covered plans' compliance with the applicable requirements related to the risk adjustment program in subparts G and H of part 153. A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.[74] For example, HHS may require an issuer to submit data pertaining to a specific data submission (for example, capitated claims). Unlike the compliance review authority established in § 156.715, which is limited to QHP issuers participating in FFEs, the compliance review authority we propose to codify in the amendments to § 153.620(c) would apply to all issuers of risk adjustment covered plans. We believe this flexibility is necessary and appropriate to provide a mechanism for HHS to address situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of issuers of risk adjustment covered plans, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. As noted above, at this time, we anticipate focusing our audit and compliance review activities under § 153.620(c) on ensuring compliance with requirements applicable to the high-cost risk pool payments under the HHS risk adjustment methodology.

Specifically, we propose to rename § 153.620(c) to ''Audits and Compliance Reviews'' in order to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate risk adjustment covered plans' compliance with the applicable requirements in subparts G and H of part 153. We similarly propose to update the introductory language in paragraph (c) to incorporate a reference to HHS compliance reviews and to note that we would conduct these compliance reviews consistent with the standards set forth in 45 CFR 156.715.

We also propose to amend the existing introductory language in § 153.620(c) to remove the last sentence that discusses audit results and the accompanying requirements that an issuer must follow if an audit results in a finding of material weakness or significant deficiency. As detailed further below, we propose to replace this with a new proposed framework that captures more details on the audit process and requirements for risk adjustment covered plans. As amended, the introductory language at paragraph (c) would reflect the authority for HHS or its designee to audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with the applicable requirements of subparts G and H of part 153. We also propose to move the existing introductory language in paragraph (c) requiring an issuer to ensure its relevant contractors, subcontractors, and agents cooperate with audits to a new proposed section, as detailed further below.

We propose to add new paragraph (c)(1) to establish notice and conference requirements for these audits. The introductory language in proposed new paragraph (c)(1) reflects that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan. In new proposed paragraph (c)(1)(i), we propose to codify that all audits under this section would include an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Further, HHS proposes to amend § 153.620(c) to add paragraph (c)(2) to capture the requirements issuers must meet to comply with an audit under this section. Under the proposed paragraph (c)(2)(i), we propose to capture the requirement that currently appears in the introductory text of paragraph (c) for the issuer to ensure that its relevant agents, contractors, and subcontractors cooperate with any audit or compliance review under this section and also propose to expand it to similarly require the issuer to ensure its relevant employees, downstream entities and delegated entities also cooperate with any audit or compliance review under this section. In new proposed paragraph (c)(2)(ii), we propose to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit. Specifically, such data would need to support the appropriateness and accuracy of the risk adjustment transfers (including high-cost risk pool payments and charges) under review as part of the audit. For example, HHS may request that issuers of risk adjustment covered plans provide enrollment and claims files and plan reference data and associated enrollee data.

In new paragraph (c)(2)(ii), we propose that issuers must submit audit data, in the format and manner specified by HHS, no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (c)(1)(i). For example, HHS may require issuers to submit the requested audit data via Electronic File Transfer. Additionally, under proposed paragraph (c)(2)(iii), HHS proposes to require that issuers respond to any audit notices, letters, and inquires, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We believe that the proposed requirements in paragraph (c)(2) are necessary and appropriate to ensure the timely completion of audits and to prevent waste that results from repeated, fruitless attempts by HHS to obtain necessary data.

Recognizing that there may be situations that warrant an extension of the timeframes under § 153.620(c)(2)(ii) or (iii), as applicable, we propose to also add a new paragraph (c)(2)(iv) to establish a process for issuers to request an extension for good cause. To request an extension, we propose to require the issuer to submit a written request to HHS within the applicable timeframe established in paragraph (c)(2)(ii) or (iii). The written request would have to detail the reasons for the extension request and the good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS' notice granting the extension of time.

Under § 153.620(c)(3), HHS proposes that it would share its preliminary audit findings with the issuer, and further proposes that the issuer would then have 30 calendar days to respond to such findings in the format and manner specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. Additionally, we propose under paragraph (c)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings

[74] For further details, please see 78 FR 65100.

within 30 calendar days, the audit findings would become final. We propose under paragraph (c)(3)(ii) that if the issuer timely responds and disputes any audit finding within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

HHS proposes to add a new § 153.620(c)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We note that the actions set forth in the final audit reports could require an issuer to return risk adjustment (including high-cost risk pool) payments, or pay increased risk adjustment (including high-cost risk pool) charges. We maintain the regulatory requirements for corrective action plans for risk adjustment (including high-cost risk pool) audits that currently appear in § 153.620(c) in new proposed paragraph (c)(4), which states that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

Lastly, if an issuer fails to comply with the audit requirements set forth in proposed § 153.620(c)(2) HHS proposes in paragraph (c)(5)(i) that HHS would notify the issuer of payments received that the issuer has not adequately substantiated, and in new proposed paragraph (c)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated. Therefore, the continued failure to comply with the audit requirements and provide the necessary information to substantiate the transfer amounts under review could result in HHS recouping up to 100 percent of the risk adjustment (including high-cost risk pool) payments, or increased risk adjustment (including high-cost risk pool) charges, made to an issuer for the applicable benefit year(s) that are the subject of the audit.

We note that any risk adjustment payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis similar to the process for risk adjustment default charge allocations to the other issuers participating in the applicable state market risk pool in the applicable benefit year.[75] We note that any high-cost risk pool payments or charges recovered by HHS during an audit of a risk adjustment covered plan would be paid on a pro rata basis to other issuers in the relevant national market in the form of a reduced high-cost risk pool charge in the applicable benefit year. HHS would not, however, re-run or otherwise recalculate transfers for the applicable benefit year if monies are recouped as a result of an audit under § 153.620(c).

We seek comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes for issuers to respond to audit notices, reports, and requests for supplemental information, and the process for issuers to request an extension to respond to such requests.

5. EDGE Discrepancy Materiality Threshold

As stated in § 153.710(a) through (c), an issuer of a risk adjustment covered plan must provide to HHS, through their EDGE server,[76] access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS for a benefit year. Consistent with § 153.730, to be considered for risk adjustment payments and charges, issuers of risk adjustment covered plans must submit their respective EDGE data by April 30 of the year following the applicable benefit year. At the end of the EDGE data submission process, HHS issues final EDGE server reports[77] which reflect an issuer's data that was successfully submitted by the data submission deadline. Within 15 calendar days of the date of these final EDGE server reports, the issuer must confirm to HHS that the information in the final EDGE server reports accurately reflect the data to which the issuer has provided access to HHS through its EDGE server for the applicable benefit year by submitting an attestation; or the issuer must describe to HHS any discrepancies it identifies in the final EDGE server reports.

HHS reviews all reported EDGE discrepancies to evaluate the implications of each incorrect data submission for risk adjustment transfers and risk adjustment data validation. For risk adjustment transfers calculated under the state payment transfer formula, HHS evaluates whether the reported EDGE discrepancy is material and has a process to address incorrect EDGE data submissions that have a material impact on risk adjustment transfers for a state market risk pool.[78] [79] Currently, HHS uses the same materiality threshold for reconsideration requests set forth in § 156.1220(a)(2) for determining whether the EDGE discrepancy has a material impact on the risk adjustment transfers calculated under the state payment transfer formula. Consequently, the reported EDGE discrepancy is considered material if the amount in dispute is equal to or exceeds the lower of either $10,000 or one percent of the total estimated transfers in the applicable state market risk pool. After analyzing reported EDGE discrepancies in prior benefit years, we propose to codify a materiality threshold for EDGE discrepancies and also propose to establish a higher materiality threshold for EDGE discrepancies. More specifically, we propose the following materiality threshold for EDGE discrepancies: The amount in dispute must equal or exceed $100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less.[80] Where an identified material EDGE discrepancy negatively affects the issuer without having a negative effect on other issuers within the state market risk pool, issuers

[75] See the 2016 Payment Notice final rule, 80 FR 10780–10781.

[76] This is also known as the dedicated distributed data collection environment.

[77] These reports are: Enrollee (Without) Claims Summary (ECS), Enrollee (Without) Claims Detail (ECD), Frequency Report by Data Element for Medical Accepted Files (FDEMAF), Frequency Report by Data Element for Pharmacy Accepted Files (FDEPAF), Frequency Report by Data Element for Supplemental Accepted Files (FDESAF), Frequency Report by Data Element for Enrollment Accepted Files (FDEEAF), Claim and Enrollee Frequency Report (CEFR), High Cost Risk Pool Summary (HCRPS), High Cost Risk Pool Detail Enrollee (HCRPDE), Risk Adjustment Claims Selection Summary (RACSS), Risk Adjustment Claims Selection Detail (RACSD), Risk Adjustment Transfer Elements Extract (RATEE), Risk Adjustment Risk Score Summary (RARSS), Risk Adjustment Risk Score Detail (RARSD), Risk Adjustment Data Validation Population Summary (RADVPS), Risk Adjustment Payment Hierarchical Condition Category Enrollee (RAPHCCER), Risk Adjustment User Fee (RAUF).

[78] See, for example, *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-2019-QQ-Guidance.pdf.* Also see 83 FR 16970 through 16971.

[79] HHS may also take action on reported material EDGE discrepancy if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

[80] We are not proposing any changes to the materiality threshold for reconsideration requests in § 156.1220(a)(2).

would be required to adhere to the initial data submission and accept the consequences of the data submission, even when the monetary impact of the inaccuracy on the issuer submitting incorrect data is potentially substantial. Therefore, HHS would generally only take action on material discrepancies that harm other issuers in the same state market risk pool.[81]

We propose to amend § 153.710, by creating new paragraph (e) and redesignating paragraphs (e), (f) and (g), as (f), (g) and (h) respectively, to capture the proposed EDGE discrepancy materiality threshold and propose to apply it beginning with the 2020 benefit year.[82] We believe this increased materiality threshold will reduce burden on issuers having to submit additional data to HHS when a discrepancy is determined to be potentially material and allow more certainty and stability for risk adjustment transfers. If a reported EDGE discrepancy is determined to not meet the materiality threshold, HHS would take no action on the discrepancy and the issuer's data submission would remain as submitted by the data submission deadline for the applicable benefit year.

While HHS generally only takes action on reported material EDGE discrepancies that are determined to harm other issuers, issuers must continue to report and describe any identified EDGE discrepancy to HHS in a format specified by HHS for each benefit year. Issuers must report all data discrepancies in order to permit HHS to determine whether such an error is material and actionable and to evaluate the impact on other issuers in the state market risk pool. We seek comment on this proposal.

6. Risk Adjustment User Fee for 2022 Benefit Year (§ 153.610(f))

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. As noted previously in this proposed rule, for the 2022 benefit year, HHS will be operating the 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.[83] 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.

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 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 2021 Payment Notice, we calculated the federal administrative expenses of operating the risk adjustment program for the 2021 benefit year to result in a risk adjustment user fee rate of $0.25 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 2022 benefit year, we propose to use 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 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 2022 benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of states for the 2022 benefit year will be approximately $60 million, and the risk adjustment user fee would be $0.25 PMPM. The risk adjustment user fee costs for the 2022 benefit year are expected to remain steady from the prior 2021 benefit year estimates. However, we project a small decline in billable member months in the individual and small group markets overall in the 2022 benefit year based on the declines observed in the 2019 benefit year. We seek comment on the proposed risk adjustment user fee for the 2022 benefit year. We will continue to examine the costs and enrollment projections for the 2022 benefit year, particularly as we receive more information on the impact of the coronavirus disease 2019 (COVID–19) PHE, and propose to incorporate any such newly available data to update the final 2022 benefit year risk adjustment user fee rate that we would announce in the final rule. We seek comment on these estimates and the use of any newly available data to update the estimates to reflect any emerging cost or enrollment trends for the final 2022 benefit year user fee.

7. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§ 153.630)

To ensure the integrity of the HHS-operated risk adjustment program, HHS conducts risk adjustment data validation (HHS–RADV) under §§ 153.350 and 153.630 in any state where HHS is operating risk adjustment on a state's behalf. The purpose of HHS–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. HHS–RADV 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 assess charges to issuers with plans with lower-than-average actuarial risk while making payments to issuer with plans with higher-than-average actuarial risk. HHS–RADV consists of an initial validation audit and a second validation audit.[84] Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of

[81] Consistent with the current process, HHS may also take action on reported material EDGE discrepancies if the discrepancy involved a processing error by HHS, HHS's incorrect application of the relevant methodology, or a HHS mathematical error, consistent with the bases upon which an issuer may request reconsideration under § 156.1220.

[82] The deadline for submission of 2020 benefit year risk adjustment data is April 30, 2021. See 45 CFR 153.730. As such, the EDGE discrepancy reporting process for the 2020 benefit year will not begin until May 2021.

[83] 78 FR 15416 through 15417.

[84] 45 CFR 153.630(a) through (c).

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.

a. Exemptions From HHS–RADV (§ 153.630(g))

In 2020 Payment Notice, we codified several exemptions from the HHS–RADV requirements. In this rule, we propose to codify the previously established exemption [85] for issuers who only offer small-group carryover coverage in the state during the benefit year being audited at new proposed § 153.630(g)(4). As we discussed in the 2020 Payment Notice, under this policy, a small group market issuer with off-calendar year coverage who exits the market but has only carry-over coverage that ends in the next benefit year (that is, carry-over of run out claims for individuals enrolled in the previous benefit year, with no new coverage being offered or sold in the state) would be considered an exiting issuer and would be exempt from HHS–RADV for the benefit year with the carry-over coverage.[86]

We also propose to codify the previously established exemption [87] for issuers who are the sole issuer in a state market risk pool during the benefit year that is being audited at new proposed § 153.630(g)(5). As we discussed in the 2020 Payment Notice, for single issuer market risk pool(s), there are no risk adjustment transfers calculated under the state payment transfer formula and thus, no payment or financial accountability to other issuers for that risk pool.[88] As such, a sole issuer in a state market risk pool is not required to participate in the HHS-operated risk adjustment program (except for purposes of high-cost risk pool payments and charges) for that state market risk pool. However, if the sole issuer was participating in multiple risk pools in the state during the year that is being audited, that issuer will be subject to HHS–RADV for those risk pools with other issuers that had risk adjustment transfers calculated under the state payment transfer formula.

These exemptions do not introduce new policies; instead, the proposed amendments to § 153.630(g) are simply to codify these previously established exemptions in regulation. We also clarify that any issuer that qualifies for the small group carryover coverage exemption in new proposed paragraph (g)(4) would not have its risk score and its associated risk adjustment transfers adjusted due to its own risk score error rate, as the issuer would not have participated in HHS–RADV for the benefit year in which it only offered the small group carryover coverage. However, that issuer's risk score and resulting risk adjustment transfers could be subject to HHS–RADV adjustments if other issuers in that state market risk pool were outliers and received HHS–RADV risk score error rates for that benefit year.

We solicit comments on these proposals.

b. IVA Requirements (§ 153.630(b)(3))

In accordance with § 153.630(b)(3), an issuer must ensure that its IVA Entity is reasonably free of conflicts of interest, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question. In prior rulemaking, we explained that to meet this standard, the IVA Entity, among other things, may not have had a role in establishing any relevant internal controls of the issuer related to the risk adjustment data validation process when HHS is operating risk adjustment on behalf of a state, or serve in any capacity as an advisor to the issuer regarding the IVA.[89] In this proposed rule, we propose to amend this standard and clarify that in order to demonstrate that the IVA Entity is reasonably free of conflicts, the IVA Entity must also not have or previously have had a role in establishing any relevant internal controls of the issuer related to risk adjustment or the EDGE server data submission process for the applicable benefit year for which the IVA Entity is performing the IVA on behalf of the issuer. Additionally, the IVA Entity must also not have served in any capacity as an advisor to the issuer regarding the risk adjustment or EDGE server data submission for the applicable benefit year. For example, the IVA Entity cannot serve as the issuer's third party administrator (TPA) for purposes of the EDGE data submission for HHS-operated risk adjustment in the 2020 benefit year and serve as the IVA Entity for that issuer for the 2020 benefit year. We are proposing these changes because HHS is concerned about conflicts of interest that could arise if the same entity assists or completes the EDGE data submissions for an issuer for an applicable benefit year, and then also serves as the IVA Entity auditing the submission of that data in HHS–RADV. This proposal is in addition to the requirements set forth in 2014 and 2015 Payment Notices.[90] We seek comment on this proposal.

c. HHS–RADV Administrative Appeals

In the 2015 Payment Notice, we established a three-level administrative appeals process for issuers to seek reconsideration of amounts under certain PPACA programs, including the calculation of risk adjustment charges, payments and user fees.[91] In the 2018 Payment Notice final rule, we extended this three-level administrative appeal process to permit issuers to dispute the findings of a second validation audit with respect to the 2016 benefit year HHS–RADV and beyond.[92] Issuers are not permitted to use the discrepancy reporting or administrative appeal processes under §§ 153.630(d)(2) and 156.1220, respectively, to contest the IVA findings, because HHS does not conduct the IVA or produce those results.[93] Instead, issuers should review their IVA findings and discuss any concerns with its IVA Entity prior to attesting to and submitting those results to HHS.[94] The existing regulation at § 153.630(d)(2) captures this policy. In this rule, we propose conforming amendments to paragraph (d)(3) to similarly add ''if applicable'' to the reference to an issuer's ability to appeal the findings of the second validation audit to ensure these regulatory provisions also appropriately capture this limitation.[95] As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the IVA and second validation audit will receive a Second Validation Audit Findings Report and therefore have the right to appeal the

[85] 84 FR 17503 through 17504.

[86] Ibid.

[87] 84 FR 17504.

[88] Ibid.

[89] See 79 FR 13758.

[90] The 2014 Payment Notice final rule required that that issuers ensure that IVA Entities are reasonably capable of performing the audit, the audit is completed, the auditor is free from conflicts of interest, and the auditor submits information regarding the IVA to HHS in the manner and timeframe specified by HHS. 78 FR 15410 at 15437. The 2015 Payment Notice final rule established standards and guidelines regarding the qualifications of the IVA Entity, including further details on the conflict of interest standards. 79 FR 13744 at 13758–13759.

[91] 78 FR 13818 through 13820.

[92] 81 FR 94106.

[93] Ibid.

[94] See, for example, Sections 9.1, 9.5 and 9.7 of the ''2017 Benefit Year Protocols PPACA HHS Risk Adjustment Data Validation, Version 2.0,'' August 10, 2018.

[95] As detailed further below, we propose similar conforming amendments to the references to an issuer's ability to appeal the findings of the second validation audit in 45 CFR 156.1220(a)(1) and (a)(3).

second validation audit findings.[96] We seek comment on these proposed amendments.

d. Timeline for Collection of HHS–RADV Payments and Charges

In the 2020 Payment Notice,[97] we finalized an updated timeline for the publication, collection, and distribution of HHS–RADV adjustments to transfers. This timeline allowed issuers to report HHS–RADV adjustments in a later MLR reporting year and to consider, in accordance with any guidance from the state DOIs, these adjustments in rate setting during a later benefit year (specifically, the year in which the HHS–RADV adjustments are collected and paid). Beginning with 2019 benefit year HHS–RADV, we propose to revert to the previous schedule [98] for the collection of HHS–RADV charges and disbursement of payments in the calendar year in which HHS–RADV results are released (for example, collection and disbursement of 2021 benefit year HHS–RADV adjustments would begin in summer or fall of 2023).

HHS publishes the final summary report of risk adjustment transfers (without HHS–RADV adjustments) and information on risk adjustment default charges for the applicable benefit year in the summer of the year after the applicable benefit year (typically June 30th of the year after the applicable benefit year), and issuers report those risk adjustment amounts in their MLR reports by July 31st of the year after the applicable benefit year.[99] Payment and collection of these risk adjustment transfer and default charge amounts generally occurs in August and September of the year after the applicable benefit year. HHS separately reports the HHS–RADV adjustments and information on default data validation charges for the applicable benefit year approximately one year after the final summary report of risk adjustment transfers for that benefit year is published (typically 2 years after the applicable benefit year in August).[100]

Under the current HHS–RADV timeline, HHS begins collection and disbursement of HHS–RADV adjustments and default data validation charges and allocations 2 years after announcing the HHS–RADV adjustments (for example, collection and disbursement of 2017 benefit year HHS–RADV adjustments will begin in 2021).[101] For MLR reporting purposes, under the current approach finalized in the 2020 Payment Notice, issuers will reflect the HHS–RADV adjustment amounts and default data validation charges and allocations in the MLR reporting year in which collections and payments of those amounts occur. Subject to approval by state DOIs, issuers are also permitted to reflect these amounts in rate setting for the same benefit year in which those amounts are paid or collected. For example, 2017 benefit year HHS–RADV adjustments and default data validation charges and allocations were announced in August 2019 and issuers will report these amounts in the 2021 MLR reporting year (MLR reports filed in 2022), the same year that the adjustments and default data validation charges will be collected and paid. Additionally, subject to permission by state DOIs, issuers were permitted to account for the impacts of those 2017 benefit year HHS–RADV adjustments in rate setting for the 2021 benefit year.

The current timeline was intended to address stakeholder concerns regarding the predictability of HHS–RADV adjustments, especially for the initial payment year. However, since the publication of the 2020 Payment Notice, we have received feedback stating that the extended timeline has not provided the increased flexibility intended by the policy and instead has introduced undue complexity. Specifically, stakeholders have expressed concern that this policy conflicts with state requirements for financial accounting, and can negatively impact their MLR rebate position, particularly if the issuer experiences substantial changes in enrollment over the 3-year MLR calculation period.[102]

Although the operational timelines of the risk adjustment program and the nature of HHS–RADV causes HHS–RADV results to always be at least a year behind the associated risk adjustment transfers report, we have continued to consider these issues. We adopted the current timeline to provide issuers (and states) with more options on how and when to account for the financial impacts from HHS–RADV. However, as noted above, stakeholder feedback has indicated that the approach did not achieve its policy goal and instead introduced unnecessary complexity. In this rule, we therefore propose to revert to the previous schedule for collection and disbursement of HHS–RADV adjustments and default data validation charges and begin such activities in the summer or fall of the calendar year in which HHS–RADV results are released. For example, collection of 2021 benefit year HHS–RADV adjustments and default data validation charges and disbursement of such amounts would begin in summer or fall of 2023. In support of the new proposed timeline for collection and disbursement of HHS–RADV adjustments and default data validation charges, HHS would need to release the applicable benefit year's report on HHS–RADV adjustments and default data validation charges earlier in the year so the amounts are available for issuers to use for MLR reporting purposes. We therefore also propose to release the applicable benefit year's HHS–RADV summary report no later than early summer, and require issuers to report those amounts in the MLR reports submitted by July 31st of the same calendar year in which the results are released. For example, as proposed, the summary report on 2021 benefit year HHS–RADV adjustments and default data validation charges and allocations would be released no later than early summer 2023, and issuers would be instructed to report these amounts in the 2022 MLR reporting year (MLR reports that include 2022 benefit year data that are submitted by July 31, 2023). We would then collect and disburse HHS–RADV adjustments and default data validation charges and allocations in summer or fall of the calendar year in which HHS–RADV results are released (for example, collection and disbursement of 2021 benefit year HHS–RADV adjustments and default data validation charges would begin in summer or fall of 2023). We note the Unified Rate Review Template (URRT) instructions currently permit issuers and states to consider HHS–RADV impacts in rates for the year

[96] 84 FR 17495.

[97] 84 FR 17506 through 17507.

[98] See 79 FR 13768 and 13769. Also see, for example, Table 3 in the document entitled ''Proposed Key Dates for Calendar Year 2019: Qualified Health Plan (QHP) Certification in the Federally-facilitated Exchanges (FFEs); Rate Review; and Risk Adjustment.'' Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Key-Dates-Table-for-CY2019.pdf.*

[99] The one exception is for the rare circumstances that HHS is unable to collect full risk adjustment charges in a state market risk pool or high-cost risk pool charges in a national market risk pool. In such situations, issuers receiving lesser payments can reflect the reductions in their MLR reports.

[100] HHS–RADV adjustments for the 2019 benefit year will be published under a different timeline due to the COVID–19-related delay in HHS–RADV activities for the 2019 benefit year. See *https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf.*

[101] *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/BY2017-HHSRADV-Adjustments-to-RA-Transfers-Summary-Report.pdf.*

[102] Issuer MLRs are calculated using a three-year average. See section 2718(b)(1)(B)(ii) of the PHS Act and 45 CFR 158.220(b).

when these amounts will be collected and disbursed, however if this proposal is finalized, we would remove this flexibility from the URRT instructions.

The new proposed timeline would help mitigate concerns regarding the incongruity with state financial accounting requirements, as well as potential undue impacts of HHS–RADV adjustments on MLR rebate liability, which could result from the HHS–RADV adjustments being reported outside the 3-year MLR aggregation window and thus potentially distorting the MLR experience of the benefit year to which HHS–RADV adjustments apply. This change may also help mitigate the impact of any substantial changes in enrollment between benefit years.

We propose to begin this policy with the collection and disbursement of HHS–RADV adjustments and default data validation charges for the 2019 benefit year. However, due to the delay in the 2019 benefit year HHS–RADV,[103] the timing of collections and disbursements is different for the 2019 benefit year. If finalized as proposed, HHS would publish the 2019 benefit year HHS–RADV Summary Report in early summer of 2022. HHS will also publish the 2020 benefit year HHS–RADV Summary report in early summer of 2022.[104] Issuers would be required to include any payments and charges reflected on these reports, along with risk adjustment transfers for the 2021 benefit year, in their 2021 MLR reports, which must be filed by July 31, 2022. Finally, HHS would begin collecting both 2019 [105] and 2020 HHS–RADV adjustments to transfers for non-exiting issuers along with any default data validation charges imposed for these two benefit years and disbursing related payments in late summer or early fall of 2022. Issuers would be required to report the 2019 and 2020 benefit year HHS–RADV adjustments to transfers in their MLR reports for the 2021 MLR reporting year (MLR reports that include 2021 benefit year data that are submitted by July 31, 2022). We seek comment on this proposal and whether any consideration should be made in the transition to this policy to account for 2017 and 2018 benefit year HHS–RADV collection and disbursement of payments and charges (under the current timeline) also occurring in 2021 and 2022.

e. Second Validation Audit and Error Rate Discrepancy Reporting Windows

Under § 153.630(d)(2), issuers have 30 calendar days to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy report, in the manner set forth by HHS, to dispute the foregoing. As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the IVA and SVA receive SVA findings.[106] We propose to amend paragraph (d)(2) to shorten the window to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate, or file a discrepancy, to within 15 calendar days of the notification by HHS, beginning with the 2020 benefit year HHS–RADV. The proposed shorter discrepancy reporting timeframes are intended to ensure that we can resolve as many issues as possible in advance of publication of the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable benefit year. Based on the first 2 payment years of HHS–RADV, HHS believes that this shortened window would not be overly burdensome to issuers, and that any disadvantages of this shortened window would be outweighed by the benefits of timely resolution of as many discrepancies as possible prior to the release of the Summary Report of Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers for the applicable benefit year. We further note that a 15 calendar day discrepancy reporting window is consistent with the IVA sample and EDGE discrepancy reporting windows at §§ 153.630(d)(1) and 153.710(d), respectively. We proposed shortening the discrepancy window in the 2020 Payment Notice, but did not finalize the proposal in response to comments suggesting that we revisit this proposal once we had completed a payment year of HHS–RADV.

We seek comment on the proposed shortened discrepancy windows under proposed § 153.630(d)(2).

8. Risk Adjustment Data Reporting Requirements for Future Premium Credits (§ 153.710)

As detailed earlier in this preamble, on September 2, 2020, HHS issued an interim final rule on COVID–19 wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year to align with the relaxed enforcement policy announced in guidance.[107] For the 2021 benefit year and beyond, we propose to permanently adopt these risk adjustment reporting requirements for all health insurance issuers in the individual and small group markets who elect to offer premium credits during a PHE declared by the Secretary of HHS (declared PHE) [108] if the premium credits are permitted by HHS in future benefit years. Specifically, we propose that issuers of risk adjustment covered plans that provide temporary premium credits when permitted by HHS in future benefit years must report to their EDGE servers adjusted plan premiums that reflect actual premiums billed to enrollees, taking the premium credits into account as a reduction in premiums. Elsewhere in this proposed rule, we also propose to clarify that HHS's calculation of risk adjustment payment and charges for the 2021 benefit year and beyond under the state payment transfer formula would be calculated using the statewide average premium that reflects actual premiums billed, taking into account any temporary premium credits provided as a reduction in premium for the applicable months of coverage when permitted by HHS in future benefit years.

As noted in the September, 2020 interim final rule on COVID–19, we believe that these requirements are necessary and appropriate because if HHS permitted issuers that provided premium credits to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur that financially impact individual issuers. For example, absent the requirement that issuers that offer premium credits report the adjusted, lower premium amount for risk

[103] HHS–RADV adjustments for the 2019 benefit year will be published under a different timeline due to the COVID–19-related delay in HHS–RADV activities for the 2019 benefit year. See *https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf.*

[104] In the proposed 2020 HHS–RADV Amendments Rule (85 FR 33595), we proposed a transition from the prospective application of HHS–RADV adjustments to a concurrent application beginning with 2020 benefit year HHS–RADV. In that proposed rule, we also solicited comment on an alternative timeline for the transition beginning with 2019 benefit year HHS–RADV. We believe that either of these timelines to transition to a concurrent application of HHS–RADV results is compatible with the proposal in this rule to change the timing of HHS–RADV collections and disbursements.

[105] See *https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf.*

[106] 84 FR 17495.

[107] See, for example, ''Temporary Policy on 2020 Premium Credits Associated with the COVID–19 Public Health Emergency,'' August 4, 2020. Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf.*

[108] The Secretary of the Department of HHS may, under section 319 of the PHS Act determine that: (a) A disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

adjustment purposes, an issuer with a large market share with higher-than-average risk enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same state market risk pool that owes a risk adjustment charge, and also provides premium credits to enrollees, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that reflected the actual, reduced premium charged to enrollees by issuers in the state market risk pool.

Therefore, we believe that requiring issuers that offer temporary premium credits, when permitted by HHS, to accurately report to the EDGE server the adjusted, lower premium amounts actually charged to enrollees is most consistent with existing risk adjustment program requirements and mitigates the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts charged to enrollees, while not imposing additional financial burdens on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts. We request comment on this proposal.

D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Definitions (§ 155.20)

a. Definitions of QHP Issuer Direct Enrollment Technology Provider and Agent or Broker Direct Enrollment Technology Provider

We propose to amend § 155.20 to add a definition of QHP issuer direct enrollment technology provider, which we propose to mean a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment under §§ 155.221 and 156.1230. We also propose that this definition of QHP issuer direct enrollment technology provider explicitly acknowledge that a web-broker may also provide services to QHP issuers as a QHP issuer direct enrollment technology provider to clarify that being a web-broker does not preclude that entity from providing technology services or an information technology platform to QHP issuers to facilitate QHP issuers' participation in direct enrollment. In addition, we propose to modify the current definition of direct enrollment technology provider in § 155.20 to distinguish it from the new proposed definition of QHP issuer direct enrollment technology provider by renaming the term agent or broker direct enrollment technology provider. We propose these new and modified definitions to capture the full array of potential arrangements between technology companies and entities seeking to use the direct enrollment pathways to facilitate enrollments in QHPs offered in an FFE or SBE–FP in a manner that constitutes enrollment in the Exchange. To align with these proposed new and modified definitions, we further propose to modify the definition of web-broker to replace the current last sentence, which states that the term includes a direct enrollment technology provider, to instead indicate a web-broker includes an agent or broker direct enrollment technology provider.

In the 2020 Payment Notice, we amended § 155.20 to define ''direct enrollment technology provider'' to mean ''a type of web-broker business entity that is not a licensed agent, broker, or producer under [s]tate law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221.'' [109] This definition captures instances in which an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, engages the services of or creates a technology company that is not licensed as an agent, broker, or producer to assist with the development and maintenance of a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. When the technology company is not itself licensed as an insurance agency or brokerage, the current framework establishes that these technology companies are a type of web-broker that must comply with applicable web-broker requirements under §§ 155.220 and 155.221, unless indicated otherwise.[110]

As the FFE direct enrollment program has evolved, particularly with the introduction and increased utilization of the enhanced direct enrollment (EDE) pathway, the technical requirements and expertise needed to participate in direct enrollment have become substantially more complex. As a result, technology companies are increasingly relied upon to develop, host, manage, and customize the technical platforms that underpin direct enrollment entity non-Exchange websites. Technology companies have emerged to support the participation of QHP issuers in direct enrollment, as well as agents, brokers, and web-brokers. In the context of EDE, some of these technology companies build technical platforms prior to finalizing contractual relationships with agents, brokers, web-brokers, or QHP issuers and some of these technology companies provide platforms that are used to host direct enrollment websites for both QHP issuers and agents, brokers, or web-brokers. Under the current framework, the technology company is itself a web-broker and often provides direct enrollment services under its own branding while also wanting to offer its technology platform and accompanying services to other agents, brokers, web-brokers, or QHP issuers to facilitate their respective participation in direct enrollment. As part of the services it provides as a technology company, it may offer customized direct enrollment websites that leverage its technical platform to other entities that allows for additional systems or functionality or the use of the other entity's branding. Because the current regulatory definition does not include a reference to QHP issuers, questions have arisen regarding the ability and accompanying requirements for QHP issuers to engage such entities to assist with the development and hosting of a non-Exchange website to facilitate the QHP issuer's participation in direct enrollment. For these reasons we propose to create a new definition of QHP issuer direct enrollment technology provider and update the definitions of direct enrollment technology provider and web-broker as described above, to clarify that QHP issuers can also engage the services of these technology companies and better align with the evolving business models of entities involved in the FFE direct enrollment program. We also propose to include language in the new definition of QHP issuer direct enrollment technology provider to clarify that when such entities partner with QHP issuers, they are downstream or delegated entities of the QHP issuer. This is similar to the approach adopted in § 155.221(e) for third-party auditors hired by QHP issuers or web-brokers to perform operational readiness audits. By

[109] See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters; Final rule, 84 FR 17454 at 17562 (April 25, 2019).

[110] For example, § 155.220(d)(2) exempts direct enrollment technology providers from the training requirement that is part of the annual FFE registration process for agents and brokers.

including this language, we intend to clarify and ensure that these QHP issuer direct enrollment technology providers would be subject to HHS oversight as the delegated or downstream entity of the QHP issuer, and the QHP issuer would be responsible for compliance with all applicable requirements. This approach is also intended to clarify that when providing its technology services and support, or providing access to an information technology platform, to a QHP issuer, QHP issuer direct enrollment technology providers would be subject to the rules applicable to the QHP issuer with whom they are partnering to the extent they are performing activities on behalf of the QHP issuer implicating those rules. For example, if a QHP issuer direct enrollment technology provider is assisting with the development of a non-Exchange website for a QHP issuer, the QHP issuer display requirements captured at § 156.1230(a)(1)(ii) would apply.

We seek comment on this proposal.

b. Definition of Exchanges

Since 2013, qualified individuals and qualified employers have been able to purchase QHPs—private health insurance that has been certified as meeting certain standards—through competitive marketplaces called Exchanges or Health Insurance Marketplaces. 45 CFR 155.20 defines an Exchange as a governmental agency or non-profit entity that meets the applicable standards of part 155 and makes QHPs available to qualified individuals and/or qualified employers. In this proposed rule, the word ''Exchanges'' collectively refers to, but is not limited to, the following models of Exchange: State Exchanges, also called State-based Exchanges (SBEs); Federally-facilitated Exchanges (FFEs); State-based Exchanges on the Federal platform (SBE–FPs); and the new proposed Direct Enrollment (DE) Exchanges (FFE–DEs, SBE–FP–DEs, or SBE–DEs). When we refer to ''the Exchange(s)'' and ''an Exchange,'' we are referring to Exchanges established and operated by a state (including a regional Exchange or subsidiary exchange) or by HHS.

2. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

To continue our efforts to standardize regulatory references to web-brokers, we propose to replace all references in § 155.205(c) to ''an agent or broker subject to § 155.220(c)(3)(i)'' with the term ''web-broker.'' In the 2020 Payment Notice, we amended § 155.20 to define the term ''web-broker'' [111] to mean an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, that is registered with an Exchange under § 155.220(d)(1) and develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with the selection of and enrollment in QHPs offered through the Exchange (a process referred to as direct enrollment). We also amended §§ 155.220 and 155.221 to incorporate the term web-broker as newly defined, where applicable. However, at the time we overlooked the fact that § 155.205(c) also contains several of these general references to agents and brokers subject to § 155.220(c)(3)(i) that should have been updated as part of this earlier effort to use the term web-broker as newly defined. Such references appear in § 155.205 paragraphs (c)(2)(i)(B), (c)(2)(iii)(B), (c)(2)(iv) introductory text, and (c)(2)(iv)(C). To avoid confusion and correct this oversight, we propose to standardize regulatory references to web-brokers by replacing all references in § 155.205(c) to ''an agent or broker subject to § 155.220(c)(3)(i)'' with the term ''web-broker.'' We seek comment on this proposal.

In addition, we propose to revise a requirement related to website content translations for QHP issuers and web-brokers participating in the FFE EDE program that are subject to §§ 155.205(c)(2)(iv)(B) and 155.205(c)(2)(iv)(C) respectively. Currently under §§ 155.205(c)(2)(iv)(B) and (C), QHP issuers and web-brokers are required to translate website content into any non-English language that is spoken by a limited English proficient (LEP) population that makes up 10 percent or more of the total population of the relevant state. Web-brokers are currently required to translate website content within one year of registering with the Exchange, while QHP issuers are currently required to translate website content beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year.

In this proposed rule, we propose to allow QHP issuers and web-brokers participating in the FFE EDE program additional time to come into compliance with the website content translation requirements. Specifically, we propose that a QHP issuer or web-broker participating in the FFE EDE program would have 12 months from the date the QHP issuer or web-broker begins operating its FFE-approved EDE website in the relevant state to comply with website content translation requirements under §§ 155.205(c)(2)(iv)(B) and (C) for website content added to their websites as a condition of participation in the FFE EDE program. We note this proposed flexibility would not absolve QHP issuers and web-brokers from complying with website content translation requirements under paragraphs (c)(2)(iv)(B) and (C) that is unrelated to their participation in the FFE EDE program within the applicable timeframes.[112] For example, a QHP issuer's or web-broker's implementation of the Exchange eligibility application on its website for purposes of participation in the FFE EDE program would be considered content added to its website to participate in the FFE EDE program and would be afforded the additional time for translation into applicable languages. However, QHP issuer website content that was not added to participate in the FFE EDE program and that is subject to the paragraph (c)(2)(iv)(C) requirements, such as Summaries of Benefits and Coverage or provider directories, would not be afforded additional time for translation into applicable languages. Similarly, website content related to a web-broker's participation in Classic DE that is subject to the paragraph (c)(2)(iv)(C) requirements, such as plan selection pages displaying QHPs, would not be afforded additional time for translation into applicable languages beyond the one year after the web-broker has been registered with the Exchange.

This proposed change does not alter the additional accessibility requirements QHP issuers and web-brokers must comply with under paragraphs (c)(2)(i), (ii), and (iii). This includes oral interpretation services, including telephonic interpreter services in at least 150 languages, written translations, and applicable tagline requirements for website content and documents critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. These obligations on QHP issuers and web-brokers would continue to protect individuals with LEP and assure that these entities are taking the necessary

[111] See 84 FR 17563.

[112] See also ''Guidance and Population Data for Exchange, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and § 156.250,'' March 30, 2016. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf.*

steps to provide meaningful access to LEP individuals, as required under title VI and the non-discrimination provisions contained in section 1557 of the PPACA.

In addition, this proposed revision also would not extend to QHP issuers and web-brokers approved to participate in a state that elects to use a direct enrollment option as proposed in § 155.221(j) of this rule. Under this proposed rule, QHP issuers and web-brokers that participate in a state that elects to implement the direct enrollment option as proposed in paragraph (j) of this rule would not be afforded the flexibility to delay website translations as otherwise permitted under § 155.205(c)(2)(iv)(C), with or without the proposed revisions in this rule. Thus, website content that is intended for consumers, qualified individuals, applicants, or enrollees on an enrollment website maintained by a web-broker or QHP issuer within a relevant state pursuant to new proposed § 155.221(j) must be translated into any non-English language that is spoken by a LEP population that makes up 10 percent or more of the total population of the relevant state, as soon as the web-broker or QHP issuer begins operating in that state.

We believe that providing QHP issuers and web-brokers participating in the FFE EDE program with additional time to come into compliance with the website content translation requirement for the website content added to their websites to participate in the FFE EDE program is warranted given the significant resources associated with entering a new state market and obtaining approval to participate in the FFE EDE program generally as well as the significant cost of third-party EDE audit requirements. Given these considerations, we believe that this proposed revision will provide an incentive for such entities to enter markets where there is a significant number of LEP individuals, while also ensuring that website content is accessible for individuals with LEP within a reasonable period of time. We are of the view that this flexibility will enable interested QHP issuers and web-brokers participating in the FFE EDE program to test markets before incurring significant additional translation costs. We are also of the view that this proposal would enable smaller QHP issuers and web-brokers to compete more effectively in state markets. In addition, lessening the burden on QHP issuers and web-brokers participating in the FFE EDE program should encourage entities that are interested in entering markets with large numbers of LEP individuals to focus on enhancing and tailoring services to meet the needs of consumers, qualified individuals, applicants, qualified employers, qualified employees, or enrollees. We believe this proposed change that would provide additional time for such entities to come into compliance with website content translation requirements will allow them more flexibility and time to assess the viability of a market prior to committing substantial resources to completing translations of website content added to their websites as a condition of participation in the FFE EDE program. The proposal could thereby ease entry of QHP issuers and web-brokers into relevant states, and allow costs associated with translation services and the related third-party audit to be spread out over time.

We seek comment on whether this added flexibility for QHP issuers and web-brokers participating in the FFE EDE program in relevant states could impact accessibility to Exchange coverage for LEP communities, or otherwise negatively impact the operation of and consumer access to Exchanges. In addition, we seek comment from QHP issuers and web-brokers as to whether this proposed change would foster investment in states where there is a significant LEP community and provide additional incentives for such entities to expand into relevant states. We would particularly like to hear from smaller QHP issuers and web-brokers as to whether the proposed flexibility provides sufficient time to encourage entry into states that meet the 10 percent LEP population threshold. Lastly, we seek comment from assisters about any impacts this proposed change would have on their ability to work with web-brokers and use EDE websites as proposed in § 155.220(c)(3)(iii) in this proposed rule when assisting members of the LEP community with Exchange enrollment.

3. Navigator Program Standards (§ 155.210)

Sections 1311(d)(4)(K) and 1311(i) of the PPACA require the Secretary to establish a Navigator program under which HHS awards grants to entities to conduct public education activities to raise awareness of the availability of QHPs, distribute fair and impartial information concerning enrollment in QHPs and the availability of APTC and CSRs, and facilitate enrollment in QHPs; provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate state agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange. The statute also requires the Secretary, in collaboration with states, to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial. We have implemented the statutorily required Navigator duties through regulations at §§ 155.210 (for all Exchanges) and 155.215 (for Navigators in FFEs). Certified Application Counselors (CACs) duties have been implemented through regulations at § 155.225.

We propose allowing, but not requiring, Navigators and CACs in FFEs and SBE–FPs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances and to the extent permitted by state law. For a discussion of the proposal to allow Navigators and CACs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment, please see the preamble to § 155.220.

4. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

a. Navigator and Certified Application Counselor Use of Web-broker Websites

In the 2020 Payment Notice, we proposed, but did not finalize, a modification of our policy that prohibits Navigators and CACs (together referred to here as ''assisters'') from using web-broker websites to assist with QHP selection and enrollment.[113] At the time, adoption of EDE functionality by web-brokers was still limited, and we decided to focus on the implementation and oversight of the EDE pathway before revisiting the current policy regarding assister use of web-broker websites. Since then, EDE functionality has become more user-friendly and increasingly more consumers are using the EDE pathway to enroll in Exchange coverage. Some stakeholders have continued to express interest in allowing for the use of web-broker non-Exchange websites by assisters to broaden the range of consumers these

[113] See 84 FR 17515 through 17521.

websites serve, to improve the consumer shopping and enrollment experience, and to leverage assisters' expertise in navigating more complex enrollment cases. For these reasons, we are revisiting these issues and propose to modify the current policy that prohibits assisters from using web-broker websites to assist with QHP selection and enrollment.

Our proposal would permit, but not require, assisters in FFEs and SBE–FPs to use web-broker non-Exchange websites to assist consumers with QHP selection and enrollment, provided the non-Exchange website meets certain conditions. The conditions we propose to require for these types of arrangements are designed to ensure that assisters are able to use web-broker non-Exchange websites while still meeting their statutory and regulatory obligations to provide fair, accurate, and impartial information and assistance to consumers, and that each web-broker's website captures and transmits assister data to the Exchange to facilitate HHS oversight of the entities using the EDE pathway. To promote state flexibility and autonomy, we propose to provide states with a State Exchange that does not rely on *HealthCare.gov* the discretion to permit their assisters to use web-broker non-Exchange websites. Alternatively, states with a State Exchange may instead choose to preserve the prohibition on assister use of web-broker websites.

Direct enrollment is a mechanism for approved third parties to assist consumers with QHP plan selection and enrollment through a non-Exchange website in a manner considered to be through the Exchange. Web-brokers are one of the entities eligible to become a direct enrollment entity. There are currently two direct enrollment pathways available in states with FFEs and SBE–FPs—Classic Direct Enrollment (Classic DE) and EDE. Classic DE is the original version of direct enrollment, which utilizes a 'double redirect' from a direct enrollment entity's non-Exchange website to *HealthCare.gov* where the eligibility application is submitted and an eligibility determination is made by the Exchange, and then back to the direct enrollment entity's non-Exchange website for QHP shopping and plan selection consistent with applicable requirements in §§ 155.220(c)(3)(i), 155.221, 156.265 and/or 156.1230(b). EDE is the version of direct enrollment which allows consumers to complete all steps in the application, eligibility and enrollment processes on the direct enrollment entity's non-Exchange website consistent with applicable requirements in § 155.220(c)(3)(ii), 155.221, 156.265 and/or 156.1230(b). EDE uses application programming interfaces (APIs) that are made available, owned, and maintained by CMS to transfer data between *HealthCare.gov* and the direct enrollment entity's non-Exchange website.

Web-brokers have developed innovative tools to support consumers shopping for QHP coverage through their non-Exchange websites for both Classic DE and EDE that assisters and the consumers they assist may find helpful when shopping for and enrolling in QHPs offered through Exchanges. In addition, some web-brokers have expressed interest in leveraging assisters' expertise in navigating more complex enrollment cases to provide additional support to the consumers they serve. At the same time, assisters have expressed a desire to obtain access to an improved consumer experience by leveraging innovative and unique consumer assistance tools and display features many web-brokers have developed for Classic DE and EDE. Additionally, some assisters have expressed a desire to have access to real-time information on the status of submitted applications and enrollments that is available through current EDE platform web portals to more effectively assist consumers. Although we are not proposing to require web-brokers to develop such web portals, we recognize that some web-brokers may consider developing web portals to enable assisters, with the consent of the consumer, to gain easy access to real-time information for each of the consumers they assist using a web-broker's non-Exchange website. Where a web-broker's non-Exchange website meets applicable requirements, we want to encourage this type of innovation to improve the experience for assisters and the consumers they assist with shopping for and enrolling in QHPs offered through an Exchange.

The implementation of EDE by a growing number of web-brokers has presented consumers with an additional method of applying for insurance affordability programs and selecting and enrolling in QHPs offered through Exchanges. We believe this additional enrollment pathway option should also be available to all FFE and SBE–FP assisters who provide application and enrollment assistance, when permitted under state law, provided there are safeguards in place to ensure that the information and help the assisters provide remains fair, accurate, and impartial. While we anticipate assisters and web-brokers would be most interested in exploring this flexibility for EDE, we believe assisters should also have the option to use the innovative and unique consumer-assistance tools and display features many web-brokers have developed to facilitate selection of QHPs offered through FFEs and SBE–FPs through Classic DE. We therefore clarify that this proposal, if finalized, would permit assisters in FFE and SBE–FP states to use a web-broker's non-Exchange website for Classic DE and EDE if applicable requirements are met and such arrangements are otherwise permitted under state law. As noted above, under this proposal, states with State Exchanges that do not use HealthCare.gov would also retain discretion to adopt a similar approach for assisters to permit the use of non-Exchange websites, or these states could maintain the current prohibition on the use of such websites by assisters.

We also anticipate that allowing FFE and SBE–FP assisters to use web-broker non-Exchange websites to enroll consumers in QHPs will encourage collaboration between assisters and web-brokers that will benefit consumers by providing them with the most appropriate support at each stage of the Exchange application, QHP selection, and QHP enrollment processes. We believe that it is essential for assisters to evolve by collaborating with new partners to better accomplish the shared goals of educating consumers and helping them to enroll in QHPs offered through Exchanges that best fit their needs. We further believe this proposal will empower assisters to use tools that may be available outside of the *HealthCare.gov* platform that can best help assisters to serve their consumers and expand their reach and impact.

While we believe consumers working with assisters should have access to additional options for selection of and enrollment in QHPs offered through Exchanges that may be available through web-broker non-Exchange websites, we believe it is necessary to put safeguards in place to ensure assisters working with consumers using these sites continue to comply with the statutory and regulatory standards governing their role and duties. Sections 1311(i)(3)(B) and (i)(5) of the PPACA and their implementing regulation at § 155.210(e)(2) require Navigators to provide fair, accurate, and impartial information to consumers in connection with their role. A similar requirement applies to CACs under § 155.225(c)(1). Under § 155.210(d), Navigators are also prohibited from being a health insurance issuer or issuer of stop loss insurance; a subsidiary of a health insurance issuer or issuer of stop loss

insurance; or an association that includes members of, or lobbies on behalf of, the insurance industry; or receiving any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any qualified individuals or employees in a QHP or a non-QHP. Finally, under §§ 155.210(b)(1) and (c)(1)(iv) (for all Navigators) and 155.215(a) (for Navigators in FFEs), Navigators must be free from any prohibited conflicts of interest. Similarly, CACs are prohibited under § 155.225(g)(2) from receiving any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals in a QHP or non-QHP, and are required under § 155.225(d)(2) to disclose any relationships they or their sponsoring agencies have with QHPs or insurance affordability programs, or other potential conflicts of interest. These rules help ensure that assisters remain free from any influence that might interfere with their duty to provide consumers with the fair, accurate, and impartial information they need to make informed plan choices, while not influencing a consumer's ultimate QHP selection.

We previously interpreted the requirement to provide fair, accurate, and impartial information to mean that assisters are prohibited from using a web-broker's non-Exchange website to provide QHP shopping, application, and enrollment assistance, unless the assister is using it as a reference tool to supplement the information available on *HealthCare.gov*.[114] This approach was adopted due to concerns that web-brokers are not required to provide fair, accurate, and impartial information, and are not prohibited from recommending specific products, including QHPs, to their clients. Therefore, we concluded that assisters would be unable to use a web-broker website consistent with their duty to provide fair, accurate, and impartial information. Since then, we have expanded the requirements applicable to agents and brokers (including web-brokers) facilitating enrollment of qualified individuals, qualified employers, or qualified employees in QHPs offered through the FFEs and SBE–FPs, including web-brokers that host non-Exchange websites. This includes FFE standards of conduct that apply to agents, brokers, and web-brokers participating in Classic DE and EDE, as well as those who use the *HealthCare.gov* website when assisting Exchange consumers. For example, agents and brokers (including web-brokers) must provide consumers with correct information, without omission of material fact, regarding the Exchanges, QHPs offered through the FFEs or SBE–FPs, and insurance affordability programs.[115] In addition, agents and brokers (including web-brokers) must refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminatory.[116] Finally, the web-broker's non-Exchange website must provide consumers with the ability to view all QHPs offered through the Exchange, not provide financial incentives such as rebates or giveaways, and not display QHP recommendations based on compensation the web-broker receives from QHP issuers.[117] We believe that the combination of these requirements can be relied upon to ensure that assisters are continuing to meet their statutory and regulatory obligations to provide fair, accurate, and impartial information and assistance to consumers when assisting them with selection and enrollment in QHPs offered through the FFEs when using a web-broker's non-Exchange website.

We are proposing several amendments to § 155.220 to capture the flexibility for assisters in FFE and SBE–FP states to use web-broker non-Exchange websites to assist consumers. As noted previously in this proposed rule, this proposed flexibility would extend to both Classic DE and EDE options that web-brokers may offer to assist consumers in FFE and SBE–FP states. First, we propose at paragraph (c)(3)(iii)(A) for web-broker websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), for such websites to be eligible for use by assisters when otherwise permitted under state law. We note that web-brokers may obtain all QHP information they would be required to display in FFEs and SBE–FPs for assisters to be permitted to use their websites by integrating with the FFEs' Marketplace API.

For web-brokers operating in FFE and SBE–FP states, we propose an optional annual certification process at new proposed paragraph (c)(3)(iii)(B) under which a web-broker could be certified by the Exchange by attesting to its compliance with the requirements proposed in § 155.220(c)(3)(iii)(A). We propose that the optional annual certification process would be integrated into the existing annual web-broker registration process, or could occur during another time of year. We propose to maintain a public list of approved web-brokers in FFEs or SBE–FPs and may add to that list information about whether a web-broker is certified, so that assisters may more easily identify web-broker websites they may seek to use in FFE and SBE–FP states, when such arrangements are permitted under state law.

The proposed amendments to § 155.220(c)(3)(iii)(A) also provide that if a web-broker non-Exchange website does not facilitate enrollment in all available QHPs in the state, it would be required to identify for consumers the QHPs, if any, for which the web-broker website does not facilitate enrollment by prominently displaying a standardized disclaimer provided by the Exchange, and in a form and manner specified by the Exchange. The disclaimer would state that the consumer can enroll in such QHPs through the Exchange-operated website, and would display a link to the Exchange website. We anticipate issuing further guidance on the form and manner in which the disclaimer should be displayed to ensure that it is clearly associated with any QHPs for which the web-broker does not facilitate enrollment. We are considering whether the disclaimer or a link to the disclaimer should replace the link or other mechanism the web-broker would otherwise display to allow a consumer to proceed with selecting and enrolling in a QHP, or whether the disclaimer should be displayed in some other fashion. We invite comments on what requirements should be adopted in reference to how this disclaimer should be displayed on a web-broker's non-Exchange website.

We note assisters, as part of providing information that is fair, accurate, and impartial, are prohibited from steering consumers to choose particular plans or recommend enrollment in any plan. With this general framework in mind, we encourage web-brokers who elect to make their non-Exchange websites available to assisters to consider developing innovative consumer assistance tools that could be used by assisters and the consumers they serve, including those related to displaying QHPs that are based on consumer preferences or based on algorithms that take into account unique consumer characteristics (for example, consumer's age, zip code, or family composition), but that are not based on compensation

[114] See 79 FR 30239.

[115] 45 CFR 155.220(j)(2)(i) and (l).

[116] Id.

[117] See 45 CFR 155.220(c)(3)(i)(B), (C), and (L) (extending these requirements to Classic DE) and 155.220(c)(3)(ii)(A) (extending these requirements to EDE).

that the web-broker may receive from QHP issuers. Consistent with the existing prohibition in § 155.220(c)(3)(i)(L), if a web-broker makes its non-Exchange website available to assisters, the website may not display QHP recommendations based on compensation the web-broker receives from QHP issuers.[118] Under our proposal, all of the other requirements outlined in §§ 155.220 and 155.221 that otherwise apply to web-broker non-Exchange websites would continue to apply to such websites when used by assisters. For example, a web-broker non-Exchange website made available to assisters would be required to refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminatory. In addition, the web-broker non-Exchange website would have to provide correct information, without omission of material fact, regarding the Exchanges, QHPs offered through the FFEs or SBE–FPs, and insurance affordability programs. We note that the proposed addition of § 155.220(n)(1) described in the preamble below that proposes to create flexibility for web-broker non-Exchange websites to display limited QHP details in certain circumstances and subject to certain requirements would not extend to web-broker non-Exchange websites used by assisters, which is why proposed § 155.220(c)(3)(iii)(A) begins with ''[n]otwithstanding paragraph (n)(1) of this section.''

We still believe that, for assisters to be permitted to use a web-broker's non-Exchange website, there would need to be a mechanism to capture information about assisters assisting consumers with Exchange applications or QHP enrollment on the non-Exchange website and that would transmit that data to the Exchange. For example, the web-broker would need to capture and transmit assister unique ID numbers to *HealthCare.gov*. This information is necessary to facilitate HHS oversight of the direct enrollment program and these details are collected for agents and brokers that use web-broker non-Exchange websites. In FFEs and SBE–FPs, web-brokers that offer their non-Exchange websites for use with Classic DE include the redirect to *HealthCare.gov* for consumers to complete the eligibility application, and the eligibility application on *HealthCare.gov* includes fields to capture this information and would therefore comply with such a requirement. For web-brokers participating in FFEs and SBE–FPs that offer their non-Exchange website for use with EDE, as indicated in operational guidance, specifically the EDE User Interface Question Companion Guide, the eligibility application hosted on the web-broker non-Exchange website must contain the same fields to capture information that are included in the application on *HealthCare.gov*. We do not believe a regulatory change is needed to capture this requirement, but clarify that we would interpret the existing requirements for an eligibility application hosted on the web-broker's non-Exchange website to capture the information included on the *HealthCare.gov* application to mandate that web-brokers that offer their non-Exchange website for use by assisters must have a mechanism to capture identifying information about assisters assisting consumers with Exchange applications or QHP enrollment and must transmit such information to the Exchange.

Nothing we are proposing is intended to change the prohibition at § 155.210(d)(4) on Navigators receiving any consideration, in cash, or in kind, directly or indirectly, from any health insurance issuer or issuer of stop loss insurance in connection with enrollment of any qualified individuals or qualified employees in a QHP or non-QHP, or on the parallel prohibition on CACs receiving any consideration directly or indirectly from any health insurance issuer or issuers of stop-loss insurance at § 155.225(g)(2). Therefore, if the proposed changes outlined above are implemented, all assisters using web-broker non-Exchange websites in FFE and SBE–FP states would continue to be prohibited from receiving compensation related to the enrollment assistance they provide.

We seek comment on all of these proposals.

b. QHP Information Display on Web-Broker Websites

We propose to provide flexibility to web-brokers regarding the information they are required to display on their non-Exchange websites for QHPs in certain circumstances. Currently, § 155.220(c)(3)(i)(A) requires that a web-broker non-Exchange website must disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c). To the extent that not all information required under § 155.205(b)(1) is displayed for a QHP, a web-broker must prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange website, and provide a link to the Exchange website. Section 155.220(c)(i)(D) similarly currently requires web-brokers to display all QHP data provided by an Exchange on its non-Exchange website used to participate in the FFE direct enrollment program (whether Classic DE or EDE). These display requirements have evolved over time as the Exchanges have matured. For example, in the early years of Exchange operations, we released a data file with limited QHP details (the QHP limited file) that provided web-brokers with a basic set of QHP data that could be used to satisfy the display requirement. In adopting this approach, we recognized that the Exchange may not have been able to provide web-brokers with certain data elements necessary to meet the § 155.205(b)(1) requirements, such as premium information, due to confidentiality requirements, web-broker appointments with QHP issuers, and state law. We also recognized some of the data elements, such as quality rating information, were not going to be available in the initial years of the Exchanges' operation.[119] Display of these data elements from the QHP limited file data, in combination with a standardized disclaimer (the plan detail disclaimer), became the *de facto* minimum required to satisfy the web-broker's obligation to display QHP information on its non-Exchange website.

In new proposed § 155.220(n), we propose to establish an exception to the web-broker display requirements captured at paragraphs (c)(3)(i)(A) and (D). We propose to revise paragraph (c)(3)(i)(A) to require a web-broker non-Exchange website to disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), except as permitted under § 155.220(n). We propose a similar revision to § 155.220(c)(3)(i)(D). At new proposed paragraph (n), we propose certain flexibilities regarding display of QHP information if a web-broker's non-Exchange website does not support enrollment in a QHP, except in cases where the web-broker's website is intended to be available for use by assisters consistent with proposed paragraph (c)(3)(iii)(A). In that case, the

[118] See 45 CFR 155.220(c)(3)(i)(L).

[119] See Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule, 78 FR 54069 at 54134 (August 30, 2013).

flexibility at new proposed paragraph (n) would not be available. A web-broker's non-Exchange website may not support enrollment in a QHP if the web-broker does not have an appointment with a QHP issuer and therefore is not permitted under state law to enroll consumers in the coverage offered by that QHP issuer. In such circumstances, we propose that the web-broker's non-Exchange website would not be required to provide all the information identified under § 155.205(b)(1). Instead, web-brokers would be required to display the following limited, minimum information for such QHPs: Issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information. To take advantage of this new proposed flexibility, we also propose that the web-broker's non-Exchange website would be required to identify to consumers the QHPs, if any, for which the web-broker's website does not facilitate enrollment by prominently displaying the plan detail disclaimer provided by the Exchange. The plan detail disclaimer explains that the consumer can get more information about such QHPs on the Exchange website, and includes a link to the Exchange website. We believe this proposal strikes an appropriate balance by recognizing that web-brokers may not be permitted to assist with enrollments in QHPs for which they do not have an appointment while still providing key information about all QHPs on web-broker non-Exchange websites to allow consumers to window shop and identify whether they may want to explore other QHP options. It also would minimize burdens for web-brokers by not requiring them to build functionality and processes to display all of the required comparative information listed in § 155.205(b)(1) for those QHPs for which they do not have an appointment to sell.

To more closely align the plan detail disclaimer text [120] with the intent of this proposal, we plan to issue further guidance revising the text of the disclaimer so that it can be clearly associated with any QHPs for which the web-broker website does not facilitate enrollment. For example, the current disclaimer text states, in relevant part, the web-broker ''isn't able to display all required plan information about this Qualified Health Plan at this time.'' We are considering modifying this text so that it states, in relevant part, the web-broker ''doesn't display all plan information about, and doesn't facilitate enrollment in, this Qualified Health Plan at this time.''

We invite comments on the proposed required limited, minimum QHP details that must be displayed for those QHPs that the web-broker does not facilitate enrollment in through its non-Exchange website and the proposed edits to the plan detail disclaimer text. We also seek comment on whether to require display of any additional elements identified under § 155.205(b)(1) among the limited, minimum information, such as summaries of benefits and coverage.[121]

c. Web-Broker Operational Readiness Review Requirements

We propose amendments to further clarify the operational readiness requirements applicable to web-brokers by adding a new proposed § 155.220(c)(6). In the 2018 Payment Notice final rule, we adopted rules to require web-brokers to demonstrate operational readiness, including compliance with applicable privacy and security requirements, prior to participating in the FFE direct enrollment program.[122] Our intent in codifying this requirement was to build on the onboarding and testing processes for a web-broker to be approved to use the direct enrollment pathways. We noted the expectation that additional operational readiness requirements would be established specific to EDE to account for the additional functionality associated with that pathway.[123] At the same time, we established similar requirements for QHP issuers to demonstrate operational readiness and compliance with applicable requirements prior to their use of the direct enrollment pathway.[124] In the 2020 Payment Notice, we consolidated these similar requirements from their prior locations at §§ 155.220(c)(3)(i)(K) and 156.1230(b)(2) into § 155.221(b)(4) as part of our effort to streamline requirements applicable to all direct enrollment entities.[125] In this rule, we propose to create a new proposed § 155.220(c)(6) to capture operational readiness requirements applicable to web-brokers that host non-Exchange websites to complete QHP selection or the Exchange eligibility application. In proposed paragraph (c)(6), we propose to include introductory language that reflects the requirement for a web-broker to demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in a form and manner specified by HHS, of certain information or testing processes. As reflected in proposed paragraphs (c)(6)(i) through (v), HHS may request a web-broker submit a number of artifacts or documents or complete certain testing processes to demonstrate the operational readiness of its non-Exchange website. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. The required testing processes may include enrollment testing, prior to approval or at the time of renewal, and website reviews performed by HHS to evaluate prospective web-brokers' compliance with applicable website display requirements prior to approval. To facilitate testing, prospective and approved web-brokers will have to maintain and provide access to testing environments that reflect their prospective or actual production environments. We are proposing these amendments to codify in regulation existing program requirements that apply to web-brokers that participate in the FFE direct enrollment program and are captured in the agreements executed with participating web-broker direct enrollment entities and related technical guidance.[126] We are not proposing to

[120] The current plan detail disclaimer states: ''[Name of Company] isn't able to display all required plan information about this Qualified Health Plan at this time. To get more information about this Qualified Health Plan, visit the Health Insurance Marketplace® website at HealthCare.gov.'' See also Section 5.3.2 of the ''Federally-Facilitated Exchanges (FFEs) and Federally-Facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual.'' Available at *https://www.regtap.info/uploads/library/ENR_FFEFFSHOPEnrollmentManual2020_5CR_090220.pdf.*

[121] Section 155.205(b)(1) references the following comparative QHP information: Premium and cost-sharing information, the summary of benefits and coverage, metal level, results of enrollee satisfaction surveys, quality ratings, medical loss ratio information, transparency of coverage measures, and the provider directory.

[122] See 81 FR 94176.

[123] See 81 FR 94120.

[124] See 81 FR 94152.

[125] See 84 FR 17524.

[126] See, for example, ''Updated Web-broker Direct Enrollment Program Participation Minimum Requirements,'' May 21, 2020. Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/*

Continued

extend the same requirements to QHP issuers participating in the FFE direct enrollment program, because QHP issuers, as HIPAA-covered entities, are subject to longstanding federal requirements and oversight related to the protection of PII and PHI that are not necessarily applicable to web-brokers. With HIPAA privacy and security regulations and oversight in place and applicable to QHP issuers, HHS has adopted a risk acceptance approach for QHP issuers allowing them to participate in the FFE direct enrollment program, in some cases, without imposing certain requirements that are in place for web-brokers. In addition, QHP issuers are subject to more extensive oversight by state regulators than web-brokers.

We seek comment on this proposal.

5. Standards for Direct Enrollment Entities and for Third Parties To Perform Audits of Direct Enrollment Entities (§ 155.221)

a. Direct Enrollment Entity Plan Display Requirements

We propose to revise § 155.221(b)(1) to clarify the requirements that apply when direct enrollment entities want to display and market QHPs [127] and non-QHPs. We propose that in such circumstances, the web-broker or QHP issuer must display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain proposed exceptions described below.

In the 2020 Payment Notice, we amended § 155.221(b)(1) to require direct enrollment entities to display and market QHPs and non-QHPs on separate website pages on their respective non-Exchange websites.[128] We explained that this proposal was intended to balance the goals of minimizing consumer confusion about distinct products with substantially different characteristics, and providing direct enrollment entities marketing flexibility and opportunities for innovation.[129] Similarly, we amended paragraph (b)(3) to require direct enrollment entities to limit the marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that will minimize the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not.[130] Under the existing display standards captured at paragraphs (b)(1) and (3), direct enrollment entities are required to offer an Exchange eligibility application and QHP selection process that is free from advertisements or information about non-QHPs and sponsored links promoting health insurance related products. However, under the current framework, it is permissible for a direct enrollment entity to market or display non-QHP health plans and other off-Exchange products in a section of the entity's website that is separate from the QHP web pages if the entity otherwise complies with the applicable requirements. We explained in the 2020 Payment Notice that we believe marketing some products in conjunction with QHPs may cause consumer confusion, especially as it relates to the availability of financial assistance for QHPs purchased through the Exchanges.[131] We acknowledged at that time that we may need to update these standards as new products come to market and as technologies evolve that can assist with differentiating between QHPs offered through the Exchange and other products consumers may be interested in. We also noted our belief that the convenience of being able to purchase additional products as part of a single shopping experience outweighs potential consumer confusion, if proper safeguards are in place.[132]

We propose to amend paragraph (b)(1) to refine the previously adopted policy, consistent with the original intent of minimizing consumer confusion about distinct products with substantially different characteristics, while providing direct enrollment entities with more marketing flexibility and opportunities for innovation. QHPs are required to be offered on- and off-Exchange under the guaranteed availability requirements at § 147.104. The current framework allows for direct enrollment entities to display on- and off-Exchange QHPs on the same website pages, as long as the direct enrollment entity's website makes clear that APTC and CSRs are only available for QHPs offered through the Exchange.[133] We have observed various attempts by direct enrollment entities to distinguish between on- and off-Exchange QHPs displayed on the same website pages, but believe that even good faith efforts to inform consumers about this distinction have the potential to cause confusion about which QHP a consumer should select if APTC-eligible when two instances of otherwise identical plans (that is, the on- and off-Exchange versions of the QHP) are displayed on a single website page, but only one is available with APTC. In addition, paragraph (b)(1) currently prohibits the display of off-Exchange QHPs on the same website pages as comparable non-QHP individual health insurance coverage. This creates a segmented off-Exchange plan shopping experience on direct enrollment entity websites that does not allow consumers to easily comparison shop among comparable major medical health insurance products. As described further below, the recent introduction of individual coverage HRAs increases the importance of individual health insurance coverage offered outside of the Exchange for employees whose employers offer such arrangements and also offer the opportunity to make salary reduction contributions through a cafeteria plan under section 125 of the Code, and this is part of the reason we are considering amending the current display requirements for direct enrollment entities.

We propose to revise § 155.221(b)(1) to require that direct enrollment entities display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain exceptions. Requiring that these three categories of products be displayed and marketed on separate website pages provides a more precise delineation between the three categories of products with substantially different characteristics, either in the way they can be purchased or the types of benefits they offer, while still allowing substantial flexibility in website design to facilitate the consumer's shopping experience. We propose the first product category, QHPs offered through the Exchange, must be isolated from the other categories of products to distinguish for consumers the products for which APTC and CSRs are available

Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf.

[127] As detailed in prior rulemaking, with some limited exceptions, stand-alone dental plans certified for sale on an Exchange are considered a type of QHP. See 77 FR 18315. CMS expects direct enrollment entities to follow the same requirements for stand-alone dental plan QHPs as for medical QHPs, including the applicable display and marketing requirements captured in §§ 155.220, 155.221 and 156.1230, except as proposed at new § 155.221(c)(2) in the context of off-Exchange stand-alone dental plan shopping.

[128] See 84 FR 17523 and 17524.

[129] See 84 FR 17523.

[130] Id.

[131] Id.

[132] Id.

[133] See, for example, 45 CFR 155.220(j)(2)(i) and 156.1230(a)(1)(iii).

(if eligible). We propose the second product category, individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), must be similarly distinguished from other products, because those plans represent major medical coverage that is subject to the same PPACA market-wide requirements as QHPs offered through the Exchange, but that is not available with APTC and CSRs. Therefore, distinguishing between these two categories of products by requiring that they be displayed and marketed on separate website pages will allow consumers to more easily shop for comparable major medical insurance subject to PPACA market-wide rules while maintaining the clear distinction between plans for which APTC and CSRs are and are not available. We propose that the third product category, which encompasses types of products not in the first two categories, including excepted benefits, must be displayed and marketed on one or more website pages separate from the website pages used for displaying and marketing the first two categories of products to assist consumers in distinguishing them from major medical plans. The range of products in the third category are not subject to PPACA market-wide rules and APTC and CSRs are not available with such products, and therefore they are substantially different from the plans that fall into the first two categories.

We also propose to amend § 155.221(b)(3) to include clarifying edits and to include the same exceptions detailed below as we are proposing for paragraph (b)(1). We propose to revise paragraph (b)(3) to limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that minimizes the likelihood that consumers will be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under new proposed paragraph (c)(1). This proposal removes a redundant reference to ''plan'' that was included after ''QHP,'' and adds references to ''plans'' after the references to ''products'' to use consistent language throughout paragraphs (b)(1) and (3). We are proposing the same exceptions for paragraph (b)(3) to align with the proposed changes to paragraph (b)(1) to clarify that displaying QHPs and non-QHPs on the same website page, as would be permitted under the proposed exceptions in certain circumstances, would not constitute a violation of paragraphs (b)(1) or (3).

We propose certain exceptions in new § 155.221(c) to the proposed updates to paragraphs (b)(1) and (3), because we recognize that, in some limited scenarios, consumers may be best served by being able to directly and easily compare plans offered on- and off-Exchange. As of January 1, 2020, employers may offer employees an individual coverage HRA (health reimbursement arrangement) instead of offering traditional group health coverage.[134] An individual coverage HRA may reimburse employees for medical expenses, including monthly health insurance premiums. To use the individual coverage HRA, an employee (and any eligible household members) must enroll in individual health insurance coverage, other than excepted benefits, or Medicare parts A and B or C. To satisfy this requirement, employees (and any eligible household members) can enroll in individual health insurance coverage through the Exchange or outside the Exchange. An employee and any household members offered an individual coverage HRA will be ineligible for APTC if the individual coverage HRA is affordable or if the employee and household members accept the individual coverage HRA even if it is unaffordable. If an employee and any household members offered an individual coverage HRA that is unaffordable decline the individual coverage HRA benefit, they may qualify for APTC (if otherwise eligible) if they enroll in a QHP through the Exchange. Some employees who are offered an individual coverage HRA may also be eligible, through a cafeteria plan under section 125 of the Code, to pay a portion of their health insurance premiums through tax-preferred salary reduction contributions. This type of cafeteria plan benefit may only be used in combination with off-Exchange individual health insurance coverage. Employers have flexibility to offer an employee both the individual coverage HRA and the cafeteria plan benefit instead of providing traditional tax-preferred group health coverage. However, employers may not offer employees a choice of an individual coverage HRA or traditional group health coverage.

Consumers shopping and enrolling in coverage through direct enrollment entity websites may therefore wish to see and consider additional non-QHP individual health insurance coverage (other than excepted benefits) options that are only available off-Exchange. We also believe consumers may find it difficult to determine their best option, especially when they are part of a tax household with members that may have varying eligibility for APTC, CSRs, Medicaid, CHIP, individual coverage HRAs, and cafeteria plans. For this reason, we propose to provide an exception to the new proposed display standards in § 155.221(b)(1) and (b)(3) to support the development of innovative and consumer-friendly plan comparison tools by direct enrollment entities to assist consumers in making the best choices for themselves and their families in these complex situations.

In proposed new paragraph (c)(1), we propose to allow direct enrollment entities to display and market QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated, within the website user interface or by communicating to an agent or broker assisting them, they have received an offer of an individual coverage HRA, as a standalone benefit or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage HRA using a salary reduction arrangement under a cafeteria plan, so long as certain conditions are met. As reflected in the new proposed § 155.221(c)(1), the conditions we propose to adopt include clearly distinguishing between the QHPs offered through the Exchange and the individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and prominently communicating that APTC and CSRs are available only for QHPs purchased through the Exchange, that APTC is not available to an individual who accepts an offer of an individual coverage HRA or who opts out of an affordable individual coverage HRA, and that a salary reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange.

In addition, we wish to reduce incentives that may lead to routing consumer households to off-Exchange plan shopping experiences based on overly simplistic factors such as a single member of a multi-member household having an individual coverage HRA and a cafeteria plan offer. Instead we seek to encourage direct enrollment entities to

[134] See Health Reimbursement Arrangements and Other Account-Based Group Health Plans; Final rule, 84 FR 28888 (June 20, 2019).

develop blended plan selection user interfaces that incorporate on- and off-Exchange plan options when assisting consumers who have communicated receipt of an offer of an individual coverage HRA while incorporating the proposed conditions that are designed to minimize the chance for consumer confusion about the differences between the different coverage options. For example, a direct enrollment entity exercising the flexibility under the proposed exception in § 155.221(c)(1) could clearly distinguish between on- and off-Exchange plan options by using frames, columns, different color schemes, prominent headings, icons, help text, and other visual aids to increase the chance that consumers are aware of the distinctions between the plan options. We emphasize the proposal's intent is for distinguishing and clarifying user interface elements to be clear, prominent, and difficult to ignore, and therefore the use of an obscure disclaimer in small text at the bottom of the page or behind a link would not be sufficient, for example. We note that in addition to the safeguards proposed in this rule, direct enrollment entities in the FFEs are subject to standards of conduct that require they provide consumers with correct information, without omission of material fact, regarding QHPs and insurance affordability programs, and refrain from marketing or conduct that is misleading.[135] We solicit comment on these proposals, as well as comments on alternative approaches through which direct enrollment entities may assist consumers with individual coverage enrollment when they have an offer of an individual coverage HRA.

We propose an additional exception to § 155.221(b)(1) at proposed paragraph (c)(2) to allow direct enrollment entities to display and market stand-alone dental plans certified by an Exchange but offered outside the Exchange and non-certified stand-alone dental plans on the same off-Exchange dental plan shopping website pages. Stand-alone dental plans certified by an Exchange and non-certified stand-alone dental plans should be largely comparable products among which consumers looking for dental coverage off-Exchange may wish to comparison shop. Since the proposed change at paragraph (b)(1) to allow display of all individual health insurance coverage offered outside the Exchange on the same website pages (including QHPs and non-QHPs other than excepted benefits) excludes stand-alone dental plans (since stand-alone dental plans are excepted benefits), we propose this additional exception to allow direct enrollment entities to provide a consumer-friendly off-Exchange stand-alone dental plan shopping experience where consumers can compare the full range of stand-alone dental plans on a single website page.

We propose conforming amendments to redesignate paragraphs (c) through (h) in § 155.221 as paragraphs (d) through (i) and related updates to internal cross references. As detailed below, we also propose certain amendments to the direct enrollment entity operational readiness review requirements in § 155.221(b)(4).

We request comment on these proposals.

b. Direct Enrollment Entity Operational Readiness Review Requirements

We propose to revise § 155.221(b)(4) to add additional detail on the operational readiness requirements for direct enrollment entities. Similar to the proposed web-broker operational readiness requirement at new proposed § 155.220(c)(6), we are proposing these amendments to codify in § 155.221(b)(4) more details about the existing program requirements that apply to direct enrollment entities and are captured in the agreements executed with participating web-broker and QHP issuer direct enrollment entities. We note that these proposed requirements are in addition to the operational readiness requirements for web-brokers at new proposed § 155.220(c)(6), although web-brokers may not be required to submit the documentation required under this proposal to revise § 155.221(b)(4) or they may be permitted to use the same documentation to satisfy the requirements of both operational readiness reviews depending on the specific circumstances of their participation in the direct enrollment program and the source and type of documentation. For example, a web-broker seeking to participate only in the Classic DE program would only be required to meet the operational readiness requirements at new proposed § 155.220(c)(6), whereas a web-broker seeking to participate in the EDE program may be permitted to use its third-party security and privacy audit documentation for EDE to satisfy the security and privacy audit documentation requirements of §§ 155.220(c)(6) and 155.221(b)(4) assuming the Classic DE and EDE systems and functionality were hosted in the same environments subject to the third-party audit.

In paragraph (b)(4), we propose to continue to require a direct enrollment entity to demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection. We add new proposed paragraphs (b)(4)(i) through (v) to reflect that direct enrollment entities may need to submit or complete, in the form and manner specified by HHS, a number of artifacts, documentation, or various testing or training processes. The documentation may include business audit documentation, including: Notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation may also include security and privacy audit documentation including: Interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; and vulnerability scan results. Submission of agreements between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program may also be required. Required testing may include eligibility application audits performed by HHS. The direct enrollment entity may also be required to complete online training modules developed by HHS related to the requirements to participate in the direct enrollment program.

We request comment on this proposal.

c. FFE, SBE–FP, and State Exchange Direct Enrollment Options

While CMS has taken a number of actions to reduce the burden on states in establishing State Exchanges, CMS wishes to maximize flexibility for all states to oversee their own healthcare markets and to address unique market dynamics in each state. As explained in the Exchange Establishment Rule, we recognize that states are best equipped to adapt the minimum Exchange functions to their local markets and the

[135] See 45 CFR 155.220(j)(2)(i), applicable to web-brokers, and 156.1230(b)(2), applicable to QHP issuers participating in direct enrollment. Also see ''Guidance Regarding website Display for Direct Enrollment (DE) Entities Assisting Consumers in States with Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal Platform (SBE–FPs).'' Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/DE-Entity-Standards-of-Conduct-website-Display.pdf.*

unique needs of their residents.[136] In addition, CMS recognizes that for decades, issuers, licensed agents and brokers, and web brokers have been engaging directly with consumers in offering health insurance and assisting consumers in selecting, enrolling in, and managing their coverage. In light of the success of the FFEs' classic direct enrollment and EDE pathways, which permit approved issuers and web brokers to facilitate enrollment in QHPs offered through the FFEs and SBE–FPs using non-Exchange websites, CMS is proposing to provide additional options for states that wish to promote more flexible and lower cost private-sector approaches for assisting consumers with shopping and enrolling in QHP coverage offered through Exchanges. We believe that this proposal also would allow states to continue to more effectively exercise their traditional oversight authority over health insurance markets, while enhancing the consumer experience, increasing competition, and lowering costs.

To date, Exchange application and enrollment activities have been supported through Exchange-operated websites. One of the primary advantages of this design is that consumers can access one-stop shopping for all QHPs offered through an Exchange and can access relevant details on such plans in a standardized format. Before Exchanges existed, consumers shopping for individual market health insurance who tried to search for this information would have to contact multiple issuers or visit multiple websites, and the information would often be presented inconsistently, preventing true apples-to-apples comparison shopping. Exchange-run application and enrollment websites also help to manage churn between private health insurance coverage and public programs such as Medicaid and CHIP by offering connections to those public programs for individuals who may qualify for participation.

While Exchange-operated application and enrollment websites have undoubtedly helped many consumers shop for and compare plans, they also present some significant potential disadvantages given historical and current implementation. First, it can be costly and burdensome to create and operate Exchanges, including not only the cost of designing and maintaining a complex website, but also the burden of staffing and operation of call centers that must be scaled up during each annual Open Enrollment Period (OEP), and then scaled down during lower-traffic periods. Second, the design of Exchange-operated websites also tends to result in choke points when a large number of consumers use the same website at the same time to shop for and enroll in coverage. For example, on high traffic days near the end of the annual OEP, some consumers trying to access *HealthCare.gov* have been redirected to the FFE call center or told to come back to the website at a later time to complete their enrollment due to volume, resulting in missed enrollment opportunities for some consumers. We have experienced issues with consumer facing (front-end) functions inhibiting consumer access to enrollment on *HealthCare.gov* while consumers are still able to shop for coverage through EDE and DE partners that rely on federal supporting functions (back-end), such as the processing of data matching and special enrollment period verification documentation, casework, and eligibility appeals. Although we recognize that without robust competition among EDE and DE partners, an EDE or DE partner's website may experience similar choke points due to high consumer traffic, state's flexibility to partner with more than one DE or EDE entity mitigates this risk.

Third, we believe it is inherently difficult for Exchanges to keep up with the rapid pace of innovation in e-commerce and the ever-evolving preferences of online shoppers, who are accustomed to shopping for the products they buy in a manner that is not only tailored to their specific needs, but is also aesthetically appealing and constantly refreshed. Federal contracting rules, for example, may limit the government's ability to frequently refresh and update the consumer experience. Finally, we have heard criticisms from some stakeholders that the Exchange-operated application and enrollment website model competes directly with and may crowd out market players such as web brokers, licensed agents and brokers, and issuers, dampening commercial investments in outreach and marketing by these market players to reach new consumers.

We believe that both the FFE's classic direct enrollment and EDE pathways have promoted innovation and competition in states using the *HealthCare.gov* platform and have ultimately lead to better experiences for consumers in these states. Direct enrollment, which has been in operation since the launch of the Exchange in 2013, and enhanced direct enrollment, which has been in operation since 2018, together are responsible for one-third of FFE enrollments. Today, the *Healthcare.gov* application and enrollment website and approved private sector non-Exchange websites operate side-by-side to enroll consumers in individual market QHPs offered through the FFEs and SBE–FPs. Like Exchange-operated websites, non-Exchange websites operated by direct enrollment partners in these states are required to provide standardized comparative information to assist consumers shopping for coverage.[137] Unlike FFE and SBE–FP application and enrollment websites, private sector entities, including those who participate in the FFE's classic and EDE pathways, are also able to provide assistance with a broader array of plan options, including both on- and off-Exchange plan options and ancillary products. This is an important feature for many consumers who do not qualify for PTCs due to their income, employees with an offer of an affordable individual coverage HRA, as well as employees offered both an individual coverage HRA and a cafeteria plan because the Code specifically prohibits using salary reduction contributions under a cafeteria plan to purchase on-Exchange coverage.[138] Finally, the FFE's EDE pathway helps to reduce costs to the federal government by enrolling many consumers without touching the FFEs' application intake and enrollment resources (for example, the Marketplace call center and the *HealthCare.gov* website).

To build on the success of the FFE's classic direct enrollment and EDE pathways for FFE and SBE–FP states that use *HealthCare.gov*, and to offer additional flexibility to all states, we are proposing a new opportunity for states to adapt the minimum Exchange functions to their local markets and leverage the benefits of direct enrollment to enhance the consumer experience through a private sector-focused consumer engagement and enrollment strategy. We propose to add § 155.221(j) to establish a process for states to elect a new Exchange Direct Enrollment (DE) option in which a state can request to allow private sector entities (including QHP issuers, web-brokers, agents and brokers) to operate enrollment pathways through which consumers can apply, receive an eligibility determination from the Exchange, and purchase an individual market QHP offered through the Exchange with APTC and CSRs, if otherwise eligible.

[136] See, for example, 77 FR at 18313.

[137] See, for example, 45 CFR 155.220(c)(3)(i)(A) (for web-brokers) and 156.1230(a)(1)(ii) (for QHP issuers).

[138] As detailed above there is a growing cohort of consumers who may be interested in off-Exchange coverage options.

As outlined in proposed § 155.221(j), subject to HHS approval, a state may elect for its Exchange to engage one or more entities described in paragraph (a) [139] to facilitate QHP enrollments through the Exchange. Under this option, similar to the current FFE direct enrollment program, the approved direct enrollment entities would enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange [140] and would also assist individuals in applying for and receiving eligibility determinations from the Exchange for APTC and cost-sharing for QHPs offered through the Exchange. New proposed § 155.221(j)(1) outlines proposed requirements that would apply to State Exchanges that do not rely on the federal eligibility and enrollment platform that want to pursue the SBE–DE option. New proposed paragraph (j)(2) outlines proposed requirements that would apply to states with an FFE or SBE–FP [141] that want to pursue the FFE–DE or SBE–FP–DE option. We propose that, subject to HHS approval, the SBE–DE option may be implemented in states with a State Exchange starting in plan year 2022. We propose that, subject to HHS approval, the FFE–DE and SBE–FP–DE option may be implemented in states with an FFE or SBE–FP starting in plan year 2023.

Under each of the Exchange DE options, states would be able to request to adopt a private sector-based enrollment approach as an alternative to the Exchanges' consumer-facing enrollment website (for example, *HealthCare.gov* for the FFEs). This less centralized, private sector-focused approach for enrollment would transition to websites operated by approved partners to serve as the online platform(s) through which consumers apply for and enroll in individual market QHPs offered through the Exchange in their state, as well as apply for and receive determinations of APTC and CSR eligibility for QHP coverage offered through the Exchange. An Exchange would implement a direct enrollment pathway (or pathways) with secure connections between its back-end eligibility system and the systems of approved issuers, web brokers, or agents and brokers that enable consumers to complete the single streamlined eligibility application as described in § 155.405, receive an eligibility determination from the Exchange, select a plan and enroll in a QHP, with or without APTC and CSRs (if otherwise eligible). Exchanges would continue to be responsible for meeting, and ensuring its approved direct enrollment partners meet, all applicable statutory and regulatory requirements governing application for and enrollment in QHPs. Under these DE options, the Exchange would also remain the entity responsible for making eligibility determinations, conducting required verifications of consumer application information, and determining whether an applicant is eligible for QHPs, APTCs, and CSRs. The Exchange would also continue to be responsible for sharing this information with CMS, which will continue to issue the applicable APTC to carriers on behalf of qualified individuals, and to the IRS, which will continue to administer the reconciliation of APTC on individual tax returns. Consistent with section 1311(d)(4)(F) of the PPACA and 45 CFR 155.302, under these DE options the Exchange would also continue to be responsible for conducting assessments or determinations of eligibility for Medicaid and CHIP, and refer such individuals to the appropriate state Medicaid agency for enrollment in such program(s).[142]

In proposing these options for states, we note that the applicable statutory provisions do not require either the federal government or states to operate an enrollment website. Rather, the PPACA provides that an Exchange must, at a minimum, certify plans as QHPs and make QHPs available to consumers, and facilitate the purchase of QHPs. An Exchange can continue to meet these obligations and the minimum functions outlined in the statute without operating a singular consumer-facing enrollment website. In the context of operating an internet website, we interpret the statutory language at section 1311(c)(5) and (d)(4)(C) of PPACA to require the Exchange provide consumers with the ability to view comparative information on QHP options but that the Exchange may direct consumers to other entities or resources for purposes of submitting applications for and enrolling in QHPs, with APTC and CSRs, if otherwise eligible. Exchanges in states that elect to pursue this new option would be required to continue to grant exemption certifications under section 1311(d)(4)(H) of the PPACA, as applicable; make available an electronic calculator consistent with section 1311(d)(4)(G) of the PPACA; establish a Navigator program as required under section 1311(d)(4)(K) of the PPACA; and provide for the operation of a toll-free telephone hotline under section 1311(d)(4)(B) of the PPACA.

For the FFE–DE, SBE–FP–DE, and SBE–DE options, the Exchange would make available both a basic website listing basic QHP information for comparison and a listing, with links, to approved partner websites for consumer shopping, plan selection, and enrollment activities. Consistent with section 1311(d)(4)(E) of the PPACA, the comparative plan information presented on the Exchange website would need to continue to utilize a standardized format, including the use of the uniform summary of benefits and coverage outline of coverage established under section 2715 of the PHS Act.[143] The standardized comparative information displayed on Exchange websites must also continue to include the quality ratings assigned to each QHP offered through the Exchange.[144] Through private sector partners such as web-brokers and issuers, states may pursue alternatives to *HealthCare.gov* or other centralized, state-operated Exchange enrollment websites to enhance the consumer experience and provide additional incentives for insurers and licensed agents and brokers to conduct marketing and outreach to enroll more consumers in coverage. While states may consider creating enhanced

[139] Section 155.221(a) identifies QHP issuers and web-brokers as eligible direct enrollment entities.

[140] Section 1401(a) of the PPACA added new section 36B to the Code, which provides for PTCs for eligible individuals, while section 1402 of the PPACA provides for CSRs for eligible individuals. For individuals to be eligible to receive PTCs, among other requirements, the PPACA requires that individuals be enrolled in a QHP through an Exchange. CMS has interpreted this statutory language to allow a QHP issuer to enroll an applicant who initiates enrollment directly with the QHP issuer. See § 156.1230, whereby individuals enrolling directly on the site of a QHP issuer are considered enrolled ''through an Exchange'' so long as the issuer meets applicable requirements. We adopted a similar approach to allow a web broker to enroll an applicant who seeks to enroll through the web broker's website. See § 155.220(a)(2) and (c), whereby individuals enrolling directly through the site of a web broker are considered enrolled ''through an Exchange'' so long as the web broker meets applicable requirements.

[141] As detailed further below, states with an SBE–FP can request to pursue the DE option as an SBE–FP–DE. If a state that currently operates an SBE–FP is interested in transitioning to a full State Exchange that implements this DE option, it would need to update its Blueprint accordingly, and meet statutory and regulatory requirements to become a State Exchange implementing the DE option (an SBE–DE). Such requirements include operating its own eligibility and enrollment platform rather than relying on the federal platform.

[142] Section 1311(d)(4)(F) requires Exchanges to inform individuals of eligibility requirements for Medicaid, CHIP, or any applicable State or local public programs and, if through screening of the application the Exchange determines such individuals are eligible for any such program and refer such individuals to the appropriate state Medicaid agency for enrollment in such program(s).

[143] See 45 CFR 155.205(b).

[144] See section 1311(d)(5)(D) of the PPACA and 45 CFR 155.205(b). Also see sections 1311(c)(3) and (c)(4) of the PPACA and 45 CFR 155.1400 and 1405.

commission structures or providing other market-based incentives, we also recognize the inherent incentive to issuers, web brokers, and agents and brokers that will result from removing what some stakeholders view as a dominant public-sector competitor, making them the primary channels through which individuals shop for and enroll in individual market QHPs in that state. We further recognize that consumers who apply and enroll through a direct enrollment pathway will have the benefit of assistance from a state-licensed agent or broker if they so choose. These agents and brokers will have been recognized by the relevant state as possessing the specialized expertise necessary to help consumers choose between health insurance options. We propose three options for states to pursue the new Exchange DE option as described more fully below. We also note that the proposed new flexibilities in §§ 155.205(c)(2)(iv)(B) and (C), as well as in § 155.220(n), would need to be coordinated and considered as part of a state's request to transition to the applicable Direct Enrollment option to determine to what extent these flexibilities may be made available to web-brokers approved to begin operating in an SBE–DE, FFE–DE, or SBE–FP–DE states, as proposed in § 155.221(j). For example, per requirements imposed through the Exchange Blueprint,[145] any State Exchange interested in pursuing this option would need to show that there would be at least one website available in the State that satisfies all accessibility requirements under § 155.205(c). Such website could be the State Exchange's consumer-facing website, or a website operated by a State Exchange-approved direct enrollment entity.

(1) Federally-Facilitated Exchange Direct Enrollment (FFE–DE) and State Exchange on the Federal Platform Direct Enrollment (SBE–FP–DE) Options

We propose an option for any FFE or SBE–FP state to request the use of direct enrollment as the enrollment avenue through which individual market consumers and qualified individuals can shop for and purchase a QHP offered through the Exchange in the state and apply and receive determinations of eligibility for APTC and CSRs. While SBE–FP states have the authority and responsibility for certifying QHPs and performing consumer outreach and assistance activities, because they rely on the *HealthCare.gov* eligibility and enrollment platform and website, in this respect they are more similar to the FFE–DE model than the SBE–DE model. In addition, the current FFE direct enrollment program and accompanying requirements also apply in SBE–FP states.[146]

Under the proposed FFE–DE and SBE–FP–DE options, *HealthCare.gov* would continue to provide the same standardized comparative information on QHP options that is available today. CMS also would post and maintain an up-to-date list on *HealthCare.gov* of approved direct enrollment partners operating in the state. As such, consumers would still be able to view comparative information on *HealthCare.gov* for all QHP options available in their area and would also be able to access information to connect with approved direct enrollment partners in that state. Additionally, in the event that any approved direct enrollment partner does not have the technical capability to handle a consumer application, *HealthCare.gov* would process that application.

By leveraging private sector entities and directing consumers to approved direct enrollment partners, the vast majority of consumer traffic would flow to direct enrollment partners, leaving the *HealthCare.gov* structure in place primarily to provide the supporting functions that it does today, like the processing of data matching and special enrollment period verification documentation, casework, and eligibility appeals.

As noted above, the Exchange would remain the entity responsible for making eligibility determinations and validating if an applicant is eligible for QHPs, APTCs and CSRs. The Exchange would also continue to issue the applicable APTC to carriers on behalf of qualified individuals and would share the relevant information with the IRS to facilitate the IRS' reconciliation of APTC on individual tax returns. Under this option, given that an FFE–DE state or SBE–FP–DE state would use one or more participating, federally-approved DE and EDE partners, at a minimum, the FFE privacy and security standards [147] and the FFE direct enrollment requirements [148] would continue to apply.

As outlined in new proposed § 155.221(j)(2), a state with an FFE or SBE–FP may request to pursue the FFE–DE or SBE–FP–DE option, as applicable. As outlined in this new proposed regulation, pursuant to a request from the state, HHS may partner with the requesting state to implement the direct enrollment option described in paragraph (j)(1). The FFE or SBE–FP must meet all applicable federal statutory and regulatory requirements for the operation of an Exchange, including maintaining the single, streamlined application required under § 155.405. In order to obtain HHS approval to implement this option, the state must coordinate with HHS on an implementation plan and timeline that allows for a transition period, developed at the discretion of HHS in consultation with the state, necessary to operationalize the required changes to implement this option. We propose to codify these new requirements at paragraph (j)(2)(i). Additionally, we propose to codify requirements at paragraph (j)(2)(ii), whereby the state must execute a federal agreement with HHS that includes the terms and conditions for the arrangement and which defines the division of responsibilities between HHS and the state. Further, in order to obtain HHS approval to implement the FFE–DE or SBE–FP–DE option, the state must agree to procedures developed by HHS for the collection and remittance of the monthly user fee described in § 156.50(c) in support of the responsibilities undertaken by the state and HHS. We propose to codify this new requirement at § 155.221(j)(2)(iii). Finally, we propose that the state would be required to perform and cooperate with activities established by HHS related to oversight and financial integrity requirements in accordance with section 1313 of the PPACA, including complying with reporting and compliance activities required by HHS and described in the Federal agreement entered into pursuant to paragraph (j)(2)(ii). We propose to codify this new requirement at paragraph (j)(2)(iv).

We request comment on all aspects of this proposal, including any comments related to timing, governance, and any other considerations needed to effectively operationalize this proposed option.

(2) State Exchange Direct Enrollment Option (SBE–DE)

Under the SBE–DE option, a state with a State Exchange that does not rely on the federal eligibility and enrollment platform can also elect the Exchange Direct Enrollment option to engage approved private-sector entities as the pathway for consumers in their state to apply for, and enroll in, QHPs offered

[145] See Blueprint for Approval of State-based Health Insurance Exchanges for Coverage Years Beginning on or after 2019, available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CMS-Blueprint-Application.pdf.*

[146] See, for example, 45 CFR 155.220(l) and 155.221(h).

[147] See 45 CFR 155.260, et. seq.

[148] See 45 CFR 155.220, 155.221, and 156.1230.

through the Exchange. Under this proposed option, the State Exchange would remain responsible for continuing to operate its eligibility platform and make eligibility determinations for consumers applying for APTC, CSRs and enrollment in QHPs offered through the Exchange. However, this new option would permit multiple private entities, such as a combination of web-brokers and issuers, to provide the consumer-facing resources for consumers to apply for and enroll in individual market coverage offered through the Exchange. State Exchanges that pursue this option could thereby leverage direct enrollment technology and direct consumers to approved partner non-Exchange websites to apply for APTC and CSRs, as well as select and enroll in a QHP offered through the Exchange (if otherwise eligible). In the event that no direct enrollment partner in the state has the technical capability to handle any consumer's application, the State Exchange would need to have the capability to process that application through its own consumer-facing website.

As outlined in new proposed § 155.221(j)(1), a state with a State Exchange that does not rely on the federal eligibility and enrollment platform may request approval to pursue the SBE–DE option and must submit a revised Exchange Blueprint in accordance with § 155.105(e) to do so.[149] As outlined in this new proposed regulation, the State Exchange must meet all other applicable federal statutory and regulatory requirements for the operation of an Exchange, including maintaining the single, streamlined application as described in § 155.405. Following submission of the revised Blueprint, HHS would have up to a total of 90 days [150] to review this revised submission and render a decision as to approval. We propose to codify the new requirement at § 155.221(j)(2)(ii) that, in order to obtain HHS approval, the state would need to provide HHS an implementation plan and timeline that details the key activities, milestones, and communication and outreach strategy to support the transition of enrollment operations to direct enrollment entities. States that want to pursue the SBE–DE option should coordinate with HHS early in the development process and would be encouraged to provide the implementation plan, timeline and outreach strategy in advance of the formal submission of the state's revised Exchange Blueprint. Additionally, in accordance with § 155.105(c)(2) and the new requirement proposed at § 155.221(j)(1)(ii), a transitioning SBE–DE would need to demonstrate to HHS operational readiness for the State Exchange and its proposed direct enrollment entities to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange and to enable individuals to apply for APTC and cost sharing for QHPs.

While we propose that SBE–DEs would retain the flexibility to determine their own business controls, as well as to decide the state-specific requirements and mechanisms for approval and oversight of direct enrollment entities operating in the state, we would encourage SBE–DEs to generally review and adopt processes and standards similar to the existing federal direct enrollment and EDE framework, as laid out at 45 CFR 155.220, 155.221, 156.1230, and in subregulatory guidance.[151] Moreover, we propose to codify a new requirement at § 155.221(j)(1)(iii) whereby SBE–DEs are obligated to ensure that a minimum of one approved direct enrollment entity approved by the state meets the minimum federal requirements for HHS approval to participate in the FFE federal direct enrollment programs, including requirements at 45 CFR 155.220 and 155.221. In particular, it is critical that the SBE–DE ensure at least one approved web-broker direct enrollment partner or other approved direct enrollment entity meets requirements that align with the FFE standards under 45 CFR 155.220(c)(3)(i)(A) and (D) [152] to ensure consumers have at least one option through which to view and access enrollment to all available QHPs in the state. It is also critical that the SBE–DE ensure at least one direct enrollment partner meets accessibility requirements under 45 CFR 155.205(c). If no direct enrollment in the SBE–DE states meets these requirements, the state would need to continue to operate its own Exchange website to ensure there is one enrollment pathway in the state that does. To assist states in meeting requirements for the SBE–DE option, we note that states would have the flexibility to partner with an existing, HHS-approved web-broker direct enrollment partner as a starting point to develop their own direct enrollment programs, as they are already fully-compliant with applicable federal requirements to participate in the FFE program.

We request comment on all aspects of this proposal, including any comments related to timing, governance, and any other considerations needed to effectively operationalize this option.

6. Certified Applications Counselors (§ 155.225)

We propose to allow, but not require, certified application counselors to assist consumers with applying for eligibility for insurance affordability programs an QHP enrollment through web-broker websites under certain circumstances. For a discussion of the provisions of this proposal, please see the preamble for § 155.220.

7. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)

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 and premium assistance (APTC or CSR) are requested using available data sources, if applicable, as described in § 155.320(d)(2). For any coverage year that an Exchange does not reasonably expect to obtain sufficient verification data as described in paragraph (d)(2)(i) through (iii), an alternate procedure applies. Specifically, Exchanges must select a statistically significant random sample of applicants and meet the requirements under paragraph (d)(4)(i). For benefit years 2016 through 2019, Exchanges also could use an alternative process

[149] This approach is consistent with the framework established in prior rulemakings that require a state to notify HHS and receive written approval from HHS before significant changes are made to the Exchange Blueprint. See, for example, 77 FR at 18316. Significant changes could include altering a key function of Exchange operations or other changes to the Exchange Blueprint that would have an impact on the operation of the Exchange. This includes, but is not limited to the process for enrollment in a QHP. See, for example, 76 FR at 41871.

[150] As detailed in § 155.105(e), HHS generally has 60 days after receipt of a completed request to complete its review of a significant change to an Exchange Blueprint and, for good cause, may extend the review period by an additional 30 days up to a total of 90 days.

[151] See generally CMS guidance for becoming a web-broker in the FFEs, available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/HealthInsurance-Marketplaces/Downloads/Processes-Becoming-Web-broker.pdf*.

[152] As noted above, the proposed new flexibilities in §§ 155.205(c)(2)(iv)(B) and (C), as well as in § 155.220(n), would need to be coordinated and considered as part of a state's request to transition to the applicable Direct Enrollment option. In addition to ensuring there is at least one website available in the State that satisfies all accessibility requirements under § 155.205(c), we propose there must also be at least one website available in the State through which consumers can view and enroll in all available QHPs in the state.

approved by HHS. We are continuing to explore a new alternative approach to replace the current procedures in paragraph (d)(4)(i), under which an Exchange may design its verification process to confirm that qualified individuals are not eligible for or enrolled in an eligible employer sponsored plan, disqualifying them from receiving 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 sample enrollees have been determined by HHS to have received APTC or CSRs inappropriately. We believe an approach to verifying an applicant's attestation regarding access to eligible employer sponsored coverage 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 paragraph (d)(4)(i), HHS is of the view that this methodology may not be the best approach for all Exchanges to assess the associated risk for inappropriate payment of APTC and CSRs. As such, in 2019, 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 affordable 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. We are still evaluating the results of this study to ensure the best verification process to ensure that consumers with offers of affordable coverage that meets affordability and minimum value standards through their employer are identified and do not receive APTC or CSRs inappropriately. HHS will consider changes to the verification process outlined under paragraph (d)(4) as part of future rulemaking.

As HHS continues to explore the best options for verification of employer sponsored coverage, we will continue to refrain from taking enforcement action against Exchanges that do not perform random sampling as required by paragraph (d)(4) and will extend this non-enforcement posture from plan year 2021 through plan year 2022.

8. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for APTC

We are proposing to add new flexibility to allow current Exchange enrollees and their dependents to enroll in a new QHP of a lower metal level [153] if they qualify for a special enrollment period due to becoming newly ineligible for APTC. In 2017, the Marketplace Stabilization Rule addressed concerns that Exchange enrollees were utilizing special enrollment periods to change plan metal levels based on ongoing health needs during the coverage year, negatively affecting the individual market risk pool. The Market Stabilization Rule 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.[154]

Generally, § 155.420(a)(4) provides that enrollees who newly add a household member through most types of special enrollment periods may add the household member to their current QHP or enroll them in a separate QHP,[155] 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). However, these rules include certain flexibilities to permit enrollees to change metal levels through a special enrollment period related to a change in financial assistance for coverage through the Exchange. For example, § 155.420(a)(4)(ii)(A) provides that if an enrollee and his or her dependents become newly eligible for CSRs 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 them to change to a silver-level QHP if they elect to change their QHP enrollment to ensure that they can access this new benefit.

We propose to add a new flexibility at § 155.420(a)(4)(ii)(C) to allow enrollees and their dependents who become newly ineligible for APTC in accordance with paragraph (d)(6)(i) or (ii) of this section to enroll in a QHP of a lower metal level. Under this proposal, these special enrollment periods in paragraph (d)(6)(i) and (ii) for becoming newly ineligible for APTC would be addressed in paragraph (a)(4)(ii)(C), and so they will no longer be subject to the separate rules in paragraph (a)(4)(iii). Therefore, we further propose to revise paragraph (a)(4)(iii) to include them in the list of triggering events excepted from the limitations at paragraph (a)(4)(iii). This proposal may help impacted 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 with a gold-level QHP who loses eligibility for APTC and sees an increase to his or her monthly premium payment could change to a bronze-level plan, or to catastrophic coverage if they are otherwise eligible.

This proposed change is similar to other recent amendments that we have made to the regulations at § 155.420(a)(4). For example, in response to concerns from HHS Navigators, other enrollment assisters, and agents and brokers based on their experiences with consumers who, upon losing eligibility for CSRs, could not afford cost sharing for their current silver-level QHP, In the May 14, 2020 **Federal Register** (85 FR 29204), the 2021 Payment Notice final rule amended paragraph (a)(4)(ii) to permit enrollees and their dependents who are enrolled in a silver-level QHP and who become newly ineligible for CSRs in accordance with paragraph (d)(6)(i) or (ii) to change to a QHP one metal level higher or lower than silver, beginning January 2022.

[153] Section 1302(d) of the PPACA describes the various metal levels of coverage based on AV, and section 2707(a) of the PHS Act directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which includes the requirement to offer coverage at the metal levels of coverage described in section 1302(d) of the PPACA. Consumer-facing *HealthCare.gov* content explains that metal levels serve as an indicator of ''how you and your plan split the costs of your health care,'' noting that lower levels such as bronze plans have lower monthly premiums but higher out of pocket costs, while higher levels such as gold plans have higher monthly premiums but lower out of pocket costs. See *https://www.healthcare.gov/choose-a-plan/plans-categories/.*

[154] 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 paragraphs (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 preamble.

[155] Section 155.420(a)(4)(i), (a)(4)(iii)(B), and (a)(4)(iii)(C) 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 § 156.140(b).

We are proposing this new flexibility because in recent months, we have also heard concerns from agents and brokers that some consumers who qualify for the special enrollment period in accordance with § 155.420(d)(6)(i) or (ii) because they lose eligibility for APTC based on an income increase may lose a significant amount of financial assistance without having gained enough income to continue to afford the coverage they selected when APTC was available to them. For example, consider a qualified individual who estimates an annual household income of $49,000 per year and enrolls in a gold plan during open enrollment with a $1,100 per month ($13,200 per year) premium and monthly APTC of $600. This qualified individual could experience an income increase of less than $2,000, lose APTC based on an income of more than 400 percent FPL, and be required to pay over $7,000 more annually for their current plan.[156] While this individual would qualify for a special enrollment period due to a loss of eligibility for APTC per paragraph (d)(6)(i), they would not be able to change from a gold plan to a silver or bronze plan (or to a catastrophic plan, if they were eligible) in order to pay a lower monthly premium, because paragraph (a)(4)(iii)(A) provides that these enrollees may only change to another QHP within their current plan's metal level.

Enrollees can also lose eligibility for APTC due to a change in household size, without experiencing any change in income. For example, assume a Virginia family of two parents and a 20-year old child, who has no income and is not a full-time student, applies during open enrollment in 2020 and qualifies for APTC based on a projected 2021 household income of $75,000, an amount less than 400 percent of the FPL for a household of three ($86,880 in the contiguous 48 states and DC).[157] During 2021 the child becomes employed and by May 2021 has earned enough income so that the parents will not be permitted to claim the child as a tax dependent for 2021. As a result, the family's household size for 2021 will be two instead of three as projected during open enrollment, resulting in the family's $75,000 household income falling above 400 percent of the FPL for a household of two ($68,960 in the contiguous 48 states and DC). Because those whose household income exceeds 400 percent of the FPL are ineligible for APTC, the reduction in the parents' household size due to not being permitted to claim their child as a tax dependent results in the parents' loss of APTC eligibility mid-year, and outside the annual open enrollment period.

Loss of APTC based on not being permitted to claim as a tax dependent an individual projected at open enrollment to be a tax dependent (loss of a projected tax dependent) is likely a less common challenge, because loss of a projected tax dependent who was previously enrolled in the same plan as other household members may also result in a lower premium for remaining household members. However, in some cases the decrease in premium may not be enough to make up for the loss of APTC.

In many cases, individuals enrolling in Exchange coverage during open enrollment will not anticipate experiencing a situation in the middle of the plan year like those described above. Even if they are aware that they could have a small increase in household income or lose a projected tax dependent, they may not realize that these changes could make them newly ineligible for APTC. Furthermore, sometimes these changes are not foreseeable. Additionally, it is reasonable for individuals who complete an application and then shop for coverage on *HealthCare.gov* to select a QHP based on premiums that are reduced by the APTC amount for which they are eligible at the time of plan selection, particularly if they do not realize that their financial assistance could change based on loss of a projected tax dependent or a small household income change during the coming year.

In addition to allowing enrollees to change to a plan with a lower premium based on losing a potentially significant amount of financial assistance due to a relatively small change in income or a change in household size, we also note that this proposal is necessary to protect consumers from gaps in coverage due to unaffordability because price differences between QHPs of different metal levels can be significant. For example, in states using the federal enrollment platform, on average silver plan premiums are 34 percent more expensive than bronze plan premiums, and gold plan premiums are 14 percent more expensive than silver plan premiums.[158] Our analysis suggests similar differences in State Exchanges, but we invite comment on whether this is the case and how it impacts current Exchange enrollees.

While this proposal is designed to provide Exchange enrollees who lose APTC with the chance to select lower-cost coverage, we recognize that changing to a new QHP mid-plan year may cause enrollees to incur additional out of pocket costs as a new QHP selection typically resets the deductible and other accumulators. We believe that Exchange enrollees who lose APTC eligibility are best able to weigh the trade-off between reset accumulators or maintaining an affordable monthly premium. Enrollees who qualify to make a new plan selection for an applicable special enrollment period already must consider this question. However, we request comment on whether this proposal would increase the risk that consumers will change plans without taking into account potential disadvantages, and on strategies to help mitigate this risk, such as consumer education.

Finally, we acknowledge that enrollees may lose APTC eligibility and qualify for a special enrollment period due to their APTC loss for a reason other than a change in household income or tax family size. For example, a currently-enrolled individual or household could lose APTC and qualify for the related special enrollment period due to an expired inconsistency regarding projected annual household income, or because the Exchange has information that they are eligible for or enrolled in other qualifying coverage that is considered MEC such as most Medicaid coverage, CHIP, or the Basic Health Program (BHP), through the periodic data matching process described in § 155.330(d), and therefore are ineligible for APTC. When consumers lose eligibility for APTC for these reasons, we encourage them to confirm whether the Exchange has correctly terminated their eligibility for APTC. If not, consumers' best option may be to correct the Exchange's records related to the issue that resulted in their APTC loss; for example, they could provide documentary evidence to the Exchange of their projected annual

[156] 26 CFR 1.36B–2(b)(1) provides that to be eligible for a PTC, the taxpayer's household income must be at least 100 percent but not more than 400 percent of the FPL for the taxpayer's family size for the taxable year. Per the HHS Poverty Guidelines for 2020, 400 percent of the FPL for 2020 for an individual in the contiguous 48 states and DC is $51,040.

[157] These examples use 2020 FPL information to determine APTC eligibility for 2021 because, per 26 CFR 1.36B–1(h), the FPL for computing the PTC for a taxable year is the FPL in effect on the first day of the initial or annual open enrollment period preceding that taxable year. For example, the Assistant Secretary for Planning and Evaluation (ASPE) released 2020 FPL information in January of 2020, and so 2020 FPL information applies during the 2020 open enrollment period for 2021 coverage.

[158] Calculated based on information in the ''Plan Year 2020 Qualified Health Plan Choice and Premiums in *HealthCare.gov* States'' report. Available at: *https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2020QHPPremiumsChoiceReport.pdf.*

household income that they attested to on their application and upon which their APTC amount was based, or return to their application and attest that they do not have other qualifying coverage such as Medicare, Medicaid/CHIP, or the BHP, if applicable. While HHS performs extensive outreach to ensure that consumers understand and can act on these options, some enrollees in this situation may choose to use their special enrollment period due to APTC loss to enroll in a plan of a lower metal level either instead of or in addition to addressing the issue that caused them to lose APTC. We seek comment on whether stakeholders have concerns with this possibility, and on how HHS can help ensure that enrollees who lose eligibility for APTC because of failure to provide information to the Exchange to confirm their APTC eligibility can understand and take action on steps needed to do so, even if they also have the flexibility to change to a plan of a lower metal level. Relatedly, we seek comment on whether Exchanges should limit the flexibility proposed in this rule only to enrollees who qualify for a special enrollment period because they lost APTC eligibility due to a change in household income or tax family size, and continue to apply the current rule at 155.420(a)(4)(iii)(A) to enrollees who qualify for a special enrollment period because they lost APTC for any other reason. We also seek comment on whether such a policy would impose significant additional burdens on Exchanges.

HHS believes that this proposal is unlikely to result in adverse selection, and may improve the risk pool by supporting continued health insurance enrollment by healthy individuals who would be forced to end coverage in response to an increase in premium. However, we request comment on whether there are concerns with permitting newly unsubsidized enrollees to change to any plan of a lower metal level to help them maintain coverage (for example, permitting an individual to change from a gold plan to a bronze plan), or whether we should instead only permit an enrollee to change to a plan one metal level lower than their current QHP. We also request comment from issuers on whether there are concerns about impacts such as experiencing a decrease in premium receipt from enrollees who opt to change to a lower-cost plan, or whether they view adverse selection as a possibility. We request comment from Exchanges, in particular, on implementation burden associated with this change to current plan category limitations rules, including on whether we should instead, in order to reduce this burden, permit current enrollees and currently enrolled dependents who qualify for this SEP to change to a plan of any metal level—that is, simply exempt the special enrollment periods at § 155.420(d)(6)(i) and (ii) due to becoming newly ineligible for APTC from plan category limitations altogether. We also request comment from all stakeholders, including those who have or represent individuals with preexisting conditions, on whether such a change would significantly increase risk for adverse selection.

Finally, we also considered whether to propose additional flexibility to allow enrollees and their dependents who become newly eligible for APTC in accordance with paragraph (d)(6)(i) or (ii) to change to a QHP of a higher metal level. While we recognize becoming newly eligible for APTC may increase the affordability of higher metal level plans for some individuals, we believe including this flexibility would largely exempt the special enrollment periods at paragraph (d)(6)(i) and (ii) from the rules at 155.420(A)(4)(iii), imposing risks of adverse selection for Exchanges by permitting individuals to change coverage levels in response to health status changes. Furthermore, while we believe the proposed flexibilities for individuals who become newly ineligible for APTC are needed in order to promote continuous coverage for individuals who can no longer afford their original plan choice, no similar affordability and continuous coverage concerns exist for enrolled consumers who gain APTC during the coverage year. Accordingly, at this time we are not proposing additional plan flexibility for enrollees who become newly eligible for APTC. We invite comment on whether we should consider additional flexibilities for this population in the future and the anticipated impact of such a policy.

We seek comment on these proposals.

b. Special Enrollment Periods—Untimely Notice of Triggering Event

We propose to allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event and was otherwise reasonably unaware that a triggering event occurred to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event. We also propose to allow such persons to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event. Finally, we propose conforming amendments to § 147.104(b)(2)(ii) so that these proposals would also apply to off-Exchange individual market health coverage.

In accordance with § 155.410(a)(2), an Exchange may only allow qualified individuals and enrollees to enroll in coverage during the annual open enrollment period as specified in § 155.410(e), and during special enrollment periods as specified in § 155.420. An Exchange must allow a qualified individual or enrollee to enroll in or change from one QHP to another if one of the triggering events described in § 155.420(d) occurs. Furthermore, under § 155.420(c)(1), a qualified individual or enrollee generally has until 60 days after the date of the triggering event to select a QHP. Section 155.420(c)(2) and (3), provide exceptions to this general rule under which a qualified individual or enrollee may enroll prior to the date of a triggering event. Section 155.420(c)(4) provides a final exception under which a qualified individual or enrollee may have less than 60 days to enroll. Coverage effective dates are outlined in § 155.420(b) and vary depending on the SEP triggering event, but in all cases are either on or after the date of the triggering event.

Because the time period during which a qualified individual may enroll through a special enrollment period is determined by the triggering event, a qualified individual who does not know the triggering event has occurred may not have sufficient time to enroll in coverage. Generally, the triggering events described in § 155.420(d) and related plan selection timelines under § 155.420(c) are premised on the assumption that an individual will become aware of a triggering event in time to make a plan selection within the time allotted under § 155.420(c). For example, the rules anticipate that qualified individuals or enrollees will receive timely notice of the day they will lose employer-sponsored coverage or the day they will gain a dependent such that 60 days is ample time for the individual to apply for enrollment through an applicable special enrollment period and select a plan. However, our experience operating the Federal Exchange has shown that there are circumstances in which an individual reasonably may not be aware of an event that triggers special enrollment period eligibility until after the triggering event has occurred. This proposal would allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event or was otherwise

reasonably unaware that a triggering event occurred, to qualify for an applicable special enrollment period and select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event. This proposal will also allow the qualified individual, enrollee, or dependent to choose the earliest effective date that would have been available if he or she had received timely notice of the triggering event.

For example, an employer fails to pay its share of premium for an insured employer-sponsored health plan and enters a grace period beginning April 1st, which will expire on May 31st. Because the employer intends to satisfy its premium liability before the end of the grace period, the employer does not notify participants and beneficiaries in the plan of the non-payment or the risk of termination of its employer-sponsored coverage retroactive to April 1st. The employer is unable to timely satisfy the premium debt, and the issuer of the employer-sponsored health coverage terminates coverage for the participants and beneficiaries retroactively to April 1st. Neither the employer nor the issuer of the employer-sponsored health plan notify the participants and beneficiaries of the beginning of the grace period or that coverage would be terminated as of April 1st. On July 10th, the participants and beneficiaries first receive notice from the issuer that their coverage terminated as of April 1st. In accordance with the circumstances described in 26 CFR 54.9801–6(a)(3)(i), due to the employer's failure to timely pay premiums, the participants and beneficiaries of the employer-sponsored health plan lost eligibility for the coverage and are eligible for the special enrollment period provided in § 155.420(d)(1)(i). Per paragraph (d)(1)(i), the triggering event for special enrollment periods due to loss of MEC is the last day the consumer would have coverage under his or her previous plan or coverage. But in this scenario, affected participants and beneficiaries, through no fault of their own, were not aware of their loss of MEC until more than 60 days following the last day they had coverage. Thus, without the measure we propose here, the participants and beneficiaries in this example would not be able to use the special enrollment period at paragraph (d)(1)(i), because more than 60 days had passed since the relevant triggering event without their having selected a new plan. Some participants and beneficiaries of employer-sponsored health plans experienced similar circumstances during the COVID–19 PHE and sought individual health insurance coverage through the FFEs, exposing a perceived gap in current special enrollment period rules.

Another circumstance in which an individual may not be aware that a triggering event occurred involves technical errors that block an individual from enrolling in coverage through an Exchange. Section 155.420(d)(4) specifies that an individual is eligible for a special enrollment period if, among other things, their erroneous non-enrollment in a QHP was due to an error on the part of the Exchange or one of its agents. In this case, the error itself is the triggering event, and the date it occurs serves as the beginning of the special enrollment period. However, as in the case of the loss of employer-sponsored coverage discussed above, an individual may not be aware that an error has occurred. In some cases, the Exchange may not be aware that a technical error has occurred which prevented individuals from enrolling until a subsequent investigation is conducted. This process may take several weeks, during which time an impacted individual may not be aware that they were unable to enroll due to an error and therefore qualify for a special enrollment period. There may even be cases in which an Exchange does not identify the issue and the impacted population and notify them until more than 60 days after the triggering event occurred.

We propose to amend § 155.420 by adding paragraph (c)(5) to specifically provide that if a qualified individual, enrollee, or dependent does not receive timely notice of an event that triggers eligibility for a special enrollment period under this section, and otherwise was reasonably unaware that a triggering event occurred, the Exchange must allow them to select a new plan within 60 days of the date that they knew, or reasonably should have known, of the occurrence of the triggering event. Additionally, we propose to add paragraph (b)(5) to clarify that when a qualified individual, enrollee, or dependent did not receive timely notice of an event that triggers eligibility for a special enrollment period, the Exchange must allow the such persons the option to choose the earliest coverage effective date for the triggering event under paragraph (b) that would have been available if they had received timely notice of the triggering event. In addition, we propose that the Exchange must also provide the qualified individual, enrollee or dependent the option to choose the effective date that would otherwise be available pursuant to the other provisions in paragraph (b).

Lastly, we propose a conforming edit to § 147.104(b)(2) that would incorporate these amendments by reference in the regulations governing special enrollment periods for off-Exchange coverage, so that these proposed special enrollment rules would apply to issuers of non-grandfathered coverage in the individual market, both on- and off-Exchange. We also separately propose a change § 147.104(b)(2)(ii) to clarify how the special enrollment period in § 155.420(d)(4) applies off-Exchange. This change is discussed in further detail in the preamble to part 147.

We seek comment on these proposals.

c. Cessation of Employer Contributions to COBRA as Special Enrollment Period Trigger

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) [159] (Pub. L. 99–272, April 7, 1986) provides for a temporary continuation of group health coverage following, among other circumstances, employees' separation from an employer, for reasons other than gross misconduct, in instances where such separation would otherwise cause termination of coverage. Although employees who elect to receive COBRA continuation coverage may be required by their former employer to pay their former employer's share of the premiums as well as their own,[160] such employers will sometimes pay all or a portion of their former employee's premium for part or all of the COBRA coverage period.

In accordance with the policy currently in place on the Exchanges using the Federal platform, we propose to amend § 155.420(d)(1) to state that the complete cessation of employer contributions for COBRA continuation coverage serves as a triggering event for special enrollment period eligibility.[161]

[159] *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf.*

[160] Individuals electing COBRA may also be required by their former employer to pay a 2 percent administrative fee. See *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf.*

[161] Because employers are not required to charge a 2 percent administrative fee to individuals who elect COBRA, we do not include this fee in the definition of ''employer contributions.'' For purposes of this section, if an individual enrolled in COBRA continuation coverage without employer contributions (so that the individual was responsible for 100 percent of the premiums) but was not required to pay a 2 percent administrative fee, this would not be considered an employer contribution for the purposes of the proposed special enrollment period.

The triggering event would occur as of the last day of the period for which COBRA continuation coverage was paid for, in whole or in part, by the employer. Exchange regulations at paragraph (d)(1)(i) provide that when a qualified individual or his or her dependent loses MEC as defined by § 155.20 they gain eligibility for a special enrollment period, during which they can enroll in a QHP. Paragraph (e) states that loss of MEC as described in paragraph (d)(1) includes the circumstances listed at 26 CFR 54.9801–6(a)(3)(i) through (iii). These provisions describe conditions under which someone may qualify for a special enrollment period for group health plan coverage, including paragraphs (a)(3)(i), ''Loss of eligibility for coverage,'' and (a)(3)(iii), ''exhaustion of COBRA continuation coverage.''

In implementing special enrollment periods for Exchanges using the Federal platform, HHS has provided a loss of MEC special enrollment period under § 155.420(d)(1)(i) for individuals whose COBRA costs change because their former employer completely ceases contributions and as a result they must pay the full cost of premiums. However, loss of coverage based on complete cessation of employer contributions for COBRA coverage might not have been treated as a triggering event by issuers of individual coverage off-Exchange or by State Exchanges. HHS believes it is important that individuals have access to a special enrollment period in the individual market when their former employer completely ceases contributions to COBRA continuation coverage, because the cost of COBRA continuation coverage premiums are substantial, rendering this type of coverage unaffordable for many people to whom it would be available.[162] Ensuring that this special enrollment period is widely available would help promote continuity of coverage for those who could not maintain their COBRA continuation coverage without employer subsidies. HHS therefore seeks to make this special enrollment period available throughout the individual market.

Therefore, we propose to amend § 155.420 by adding paragraph (d)(1)(v) stating that a special enrollment period is triggered when a qualified individual or his or her dependent is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums, and the employer completely ceases its contributions. Similar to the special enrollment period for termination of employer contributions to employer-sponsored coverage at 26 CFR 54.9801–6(a)(3)(ii), the triggering event would occur as of the last day of the period for which COBRA continuation coverage is paid for, in part or in full, by an employer. We also propose to make conforming changes to the preceding paragraphs to reflect the addition of this new paragraph. Furthermore, since complete cessation of employer contributions toward employer-sponsored continuation coverage under state mini-COBRA laws [163] serves as a special enrollment period triggering event under 26 CFR 54.9801–6(a)(3)(ii), which is incorporated by § 155.420(e), we propose to include in paragraph (v) a reference to this regulation for purposes of clarity. These changes would make explicit HHS's current policy with regard to the Exchanges using the Federal platform, and would ensure that individual market policies sold off-Exchange and through State Exchanges align with it. In addition, amending paragraph (d)(1) to explicitly include complete cessation of employer contributions to COBRA continuation coverage as a special enrollment period triggering event would mitigate confusion among employers and employees, as well as other stakeholders, about their options regarding COBRA continuation coverage and special enrollment period eligibility.

As with other special enrollment periods described in § 155.420(d)(1), in the Exchanges, this special enrollment period would be subject to the provisions in paragraph (a)(4)(iii)(B) and (C), which allow dependents and non-dependent qualified individuals who qualify for a special enrollment period to be added to the QHP of a household member who is already enrolled in Exchange coverage, or to enroll separately in a plan of any metal level. We also propose that the Exchange must provide the qualified individual, enrollee, or dependent the effective date that would otherwise be available pursuant to the other provisions at paragraph (b)(2)(iv). In accordance with paragraph (c)(2), an individual eligible for this special enrollment period would have 60 days before or after the triggering event (in this case, the last day for which the qualified individual or dependent has COBRA continuation coverage to which an employer is contributing) to select a QHP. We propose that this special enrollment period, which would be incorporated by reference in the guaranteed availability regulations at § 147.104(b)(2), apply with respect to individual health insurance coverage offered through and outside of an Exchange.

To help clarify the circumstances that would trigger the proposed special enrollment period, we include the following examples:

Example 1: An individual is laid off from a job in June, and enrolls in COBRA continuation coverage for which the employer pays 100 percent of the premiums (the employer does not require payment of a 2 percent administrative fee). On September 3rd of that year, the employer informs the individual that it is completely terminating contributions to the individual's COBRA continuation coverage as of September 30th, and beginning on October 1st, the individual will be responsible for 100 percent of the COBRA continuation coverage premiums. As a result, the individual decides to end COBRA coverage on October 1st. Because September 30th is the last day for which the individual had COBRA continuation coverage for which the employer was contributing, the individual has 60 days before and after this date (in this case, between August 1st and November 29th) to select an individual market plan through a special enrollment period.

Example 2: Same scenario as in the first example, except that the employer was paying only 25 percent of the COBRA continuation coverage premiums before the employer completely terminated contributions. The individual decides to maintain COBRA continuation coverage despite the loss of employer contributions. Even though the individual retained COBRA continuation coverage, the individual is still eligible to select a QHP through a special enrollment period from August 1st to November 29th, 60 days before or after the last day on which the individual had COBRA continuation coverage with employer contributions.

In addition to this proposal, HHS is also considering addressing situations in which an employer reduces, but does not completely cease, its contributions for COBRA continuation coverage. In particular, we are considering adding to proposed paragraph § 155.420(d)(1)(v) a provision that a reduction of employer contributions for COBRA continuation coverage would also serve as a special enrollment period trigger. The triggering event would occur the last day on which an individual has COBRA continuation coverage that was subsidized at the higher amount. Reduction of employer contributions to COBRA continuation coverage has not

[162] *https://www.kff.org/private-insurance/issue-brief/key-issues-related-to-cobra-subsidies/.*

[163] *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/cobra-continuation-health-coverage-consumer.pdf.*

previously been treated as a triggering event for purposes of the loss of MEC special enrollment period under paragraph (d)(1)(i). However, HHS believes it is important to address this scenario as a way of promoting continuity of coverage for those who would not be able to maintain their COBRA continuation coverage with a reduced employer contribution. A similar special enrollment period for reduction of employer contributions to employer-sponsored coverage is not currently provided for under the provisions at 26 CFR 54.9801–6(a)(3)(i) through (iii). However, HHS believes it is important to provide a special enrollment period for reductions in employer contributions toward COBRA coverage because there are differences between employer-sponsored coverage and COBRA, such as the fact that COBRA continuation coverage is not subject to an affordability test under 26 CFR 1.36B–2(c)(3)(v) for purposes of determining potential eligibility for APTC and/or CSR, and the fact that individuals must generally pay more for COBRA continuation coverage than for employer-sponsored coverage.

Because this situation is not addressed in regulation or by HHS policy, we seek comment on whether stakeholders believe it would be helpful to codify such a special enrollment period if an employer reduces, but does not completely cease, its contributions to COBRA continuation coverage. In addition, we seek comment on whether HHS should also adopt a threshold for the level of reduction of employer contributions for COBRA continuation coverage that should trigger a special enrollment period.

We seek comment on this proposal.

d. Special Enrollment Period Verification

In 2017, the HHS Market Stabilization Rule preamble explained that HHS would implement pre-enrollment verification of eligibility for certain special enrollment periods in all FFEs and SBE–FPs and encouraged states to do the same in State Exchanges. Special enrollment period verification has addressed concerns that allowing individuals to enroll in coverage through a special enrollment period without electronic or document-based verification 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.[164]

Since 2017, Exchanges using the federal platform have implemented pre-enrollment special enrollment period verification for special enrollment period types commonly used by consumers to enroll in coverage. Consumers who are not already enrolled through the Exchange and who apply for coverage through a special enrollment period type that requires pre-enrollment verification by the Exchange must have their eligibility electronically verified using available data sources, or they must submit supporting documentation to verify their eligibility for the special enrollment period before their enrollment can become effective. As stated in the HHS Marketplace Stabilization Rule, special enrollment period verification is only conducted for new enrollees due to the potential for additional burden on issuers and confusion for consumers if required for existing enrollees.

In implementing pre-enrollment verifications for special enrollment periods in the Market Stabilization Rule, HHS did not establish a regulatory requirement that all Exchanges conduct special enrollment period verifications, in order to allow State Exchanges with flexibility to adopt policies that fit the needs of their state.[165] Currently, all State Exchanges now conduct either pre- or post-enrollment verification of at least one special enrollment type, and most State Exchanges have implemented a process to verify the vast majority of special enrollment periods requested by consumers.

Therefore, we propose to amend § 155.420 to add paragraph (f) to require all Exchanges to conduct eligibility verification for special enrollment periods. Specifically, we propose to require that Exchanges conduct special enrollment period verification for at least 75 percent of new enrollments through special enrollment periods for consumers not already enrolled in coverage through the applicable Exchange. We are proposing that Exchanges must verify at least 75 percent of new enrollments through special enrollment periods based on the current implementation of special enrollment period verification by Exchanges. If the Exchange is unable to verify the consumer's eligibility for enrollment through the special enrollment period, then the consumer is not eligible for enrollment through the Exchange, and enrollment through the Exchange may be terminated in accordance with 45 CFR 155.430(b)(2)(i). If an Exchange opts to pend a plan selection prior to enrollment, and the Exchange cannot verify eligibility for the special enrollment period, then the consumer will be found ineligible for the special enrollment period, and the plan selection will not result in an enrollment. The determination of how many enrollments would constitute 75 percent would be required to be based on special enrollment period enrollment. This would provide Exchanges with implementation flexibility so they can continue to decide which special enrollment types to verify and the best way to conduct that verification. Exchanges will not be required to verify eligibility for all special enrollment periods, since the cost to verify eligibility for special enrollment period triggering events with very low volumes could be greater than the benefit of verifying eligibility for them.

We also continue the flexibility that State Exchanges currently have to design eligibility verification processes that are appropriate for their market and Exchange consumers, such that State Exchanges may have such flexibility in their approaches for meeting the requirement proposed at § 155.420(f) to verify eligibility for a special enrollment period. Specifically, under § 155.315(h), State Exchanges have the flexibility to propose alternative methods for conducting required verifications to determine eligibility for enrollment in a QHP under subpart D, such that the alternative methods proposed reduce the administrative costs and burdens on individuals while maintaining accuracy and minimizing delay. We propose to use the existing authority at § 155.315(h) to allow State Exchanges to request HHS approval for use of alternative processes for verifying eligibility for special enrollment periods as part of determining eligibility for special enrollment periods under § 155.305(b). This would allow, for instance, the smaller State Exchanges that have administrative burden and cost concerns the option to coordinate with HHS to devise and agree upon the best approach for special enrollment period verification for their specific population. We recognize that State Exchanges may vary in their approach and technical capabilities relating to verification of special enrollment periods and may need additional time to implement this requirement. Therefore, we are proposing to allow Exchanges until plan year 2024 to implement special enrollment period verification.

We seek comment on these proposals. With respect to Special Enrollment Period Verification, we seek comment

[164] 82 FR at 18356.

[165] 82 FR at 18356.

from States about the 75 percent verification threshold and whether it should be based on past year or current year special enrollment period enrollments, understanding that unforeseen events may occur that may drive up or down enrollments from year-to-year.

9. Required Contribution Percentage (§ 155.605(d)(2))

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. Accordingly, we propose the required contribution percentage for the 2022 benefit year, calculated using income and premium growth data for the 2013 and 2021 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 rule, we are proposing as the measure for premium growth the 2022 premium adjustment percentage of 1.4409174688 (or an increase of about 44.1 percent over the period from 2013 to 2021). This reflects an increase of about 6.4 percent over the 2021 premium adjustment percentage (1.4409174688÷1.3542376277).

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 ($61,156 for 2021) exceeds per capita PI for 2013 ($44,948), carried out to ten significant digits. The ratio of per capita PI for 2021 over the per capita PI for 2013 is estimated to be 1.3605944647 (that is, per capita income growth of about 36.1 percent).[166] This rate of income growth between 2013 and 2021 reflects an increase of approximately 3.9 percent over the rate of income growth for 2013 to 2020 (1.3605944647÷1.3094029651) that was used in the 2021 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.).[167]

Thus, using the 2022 premium adjustment percentage proposed in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2021 would be 1.4409174688 ÷1.3605944647, or 1.0590352278. This would result in a proposed required contribution percentage for 2021 of 8.00×1.0590352278 or 8.47 percent, when rounded to the nearest one-hundredth of one percent, an increase of 0.20 percentage points from 2020 (8.47228–8.27392).

Finally, beginning with the 2023 benefit year, we are proposing to publish the required contribution percentage, along with the premium adjustment percentage and the annual cost-sharing limitation parameters, in guidance separate from the annual notice of benefit and payment parameters. For a discussion of the provisions of this proposal, please see the preamble for Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130).

We seek comment on these proposals.

10. Excluding the Special Enrollment Period Trigger in § 155.420(d)(1)(v) From Applying to SHOP Plans (§ 155.726)

Special enrollment periods due to cessation of employer contributions to COBRA continuation coverage are generally not available in the group insurance market. Therefore, in order to maintain consistency between SHOP and the rest of the group insurance market, we propose to amend § 155.726(c)(2)(i) to exclude the special enrollment period trigger in proposed paragraph § 155.420(d)(1)(v) from applying to SHOP plans. For a discussion of the provisions of this proposal, please see the preamble for § 155.420.

We seek comment on this proposal.

E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. User Fee Rates for the 2022 Benefit Year (§ 156.50)

a. FFE and SBE–FP User Fee Rates for the 2022 Benefit Year (§ 156.50(c))

Section 1311(d)(5)(A) of the PPACA requires states to ensure that Exchanges are self-sustaining, which may include the state allowing 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

[166] The 2013 and 2021 per capita personal income figures used for this calculation reflect the latest NHEA data, published on March 24, 2020. 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 2019–2028—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 available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.*

[167] 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.*

through an FFE or SBE–FP. In addition, OMB Circular No. A–25 establishes federal policy regarding the assessment of user charges under other statutes and applies to the extent permitted by law. Furthermore, OMB Circular 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 are not covered by this user fee. As in benefit years 2014 through 2021, issuers seeking to participate in an FFE in the 2022 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.

For the 2022 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 anticipated establishment of state Exchanges in certain states in which FFEs currently are operating), and premiums for the 2021 plan year, we propose a 2022 user fee rate for all participating FFE issuers at 2.25 percent of total monthly premiums. This proposed user fee rate reflects our estimates for the 2022 benefit year of costs for operating the Federal Exchanges, premiums, enrollment, and transitions in Exchange models (from the FFE and SBE–FP models to either the SBE–FP, FFE–DE or State Exchange models (state transitions). The proposed FFE user fee rates are lower than the 3.0 percent FFE user fee rate that we established for benefit years 2020 and 2021, and the 3.5 percent FFE user fee rate that we established for benefit years 2014 through 2019. After accounting for the impact of the lower user fee rate, we estimate that we would have sufficient funding available to fully fund user-fee eligible Exchange activities. We seek comment on this proposed 2022 FFE 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 SBE–FP issuers by the federal government include use of the Federal Exchange information technology platform and call center infrastructure used to support 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. Based on this methodology, we propose to charge issuers offering QHPs through an SBE–FP a user fee rate of 1.75 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP. This proposed rate is lower than the 2.5 percent user fee rate that we had established for benefit year 2021. The lower proposed user fee rate for SBE–FP issuers for the 2022 benefit year reflects our estimates of costs for operating the Federal Exchanges, premiums, enrollment, as well as state Exchange transitions for the 2022 benefit year, and the costs associated with performing these services that benefit SBE–FP issuers. We seek comment on the proposed 2022 SBE–FP user fee rate.

b. FFE–DE and SBE–FP–DE User Fee Rates for the 2023 Benefit Year (§ 156.50(c)(3))

Elsewhere in this proposed rule, we propose to allow states served by an FFE or SBE–FP to implement the proposed direct enrollment option under § 155.221(j) beginning with plan year 2023, under which one or more private direct enrollment entities approved by the FFE would operate websites through which consumers may apply for and enroll in a QHP, with or without APTC or CSR (if otherwise eligible). Under the proposed FFE–DE or SBE–FP options, QHP issuers offering plans through the Exchange would receive some of the benefits of the Federal Exchange, however, some consumer outreach, education, and support activities would be provided by the state or through the Federal Exchange.[168]

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. As such, we propose in new § 156.50(c)(3) to charge issuers offering QHPs through an FFE–DE or an SBE–FP–DE a user fee for the services and benefits provided to those issuers by HHS as the administrator of the Federal Exchange. We propose to charge issuers offering QHPs through an FFE–DE or SBE–FP–DE a user fee rate calculated based on the proportion of FFE user fee eligible costs incurred by HHS that are associated with implementation and operation of the FFE–DE or SBE–FP–DE. We assume that the use of Federal Exchange services will be less for FFE–DE and SBE–FP–DE states in 2023 and beyond than for FFE and SBE–FP states during the same time period. Therefore, to provide some certainty for states that consider a transition to a proposed FFE–DE or SBE–FP–DE, we propose a 2023 user fee rate of 1.5 percent of the monthly premium charged by the issuer for each policy under plans offered through an FFE–DE or SBE–FP–DE in plan year 2023. Under the DE option, the Exchange would no longer be providing many of the consumer facing enrollment-related activities that are currently being performed through the Federal platform, or such activities would be substantially reduced. For

[168] See above for more information on the proposed direct enrollment option under § 155.221(j).

example, the use of the Marketplace call center and HealthCare.gov website will be substantially diminished. Because of the role of the state in operating SBE–FPs, the value to issuers and the associated costs of operating these functions in FFEs is typically higher. The reduction of these functions and costs therefore is reflected by a larger proposed reduction in the user fee rate for issuers in FFE–DEs from the rate applicable in FFEs (from 2.25 percent to 1.5 percent) than the reduction in the user fee rate for issuers in SBE–FP–DEs from the rate applicable in SBE–FPs (from 1.75 percent to 1.5 percent), resulting in the same proposed user fee rate for these new Exchange options. We seek comment on the FFE–DE or SBE–FP–DE user fee rate, including whether the rate should be state-specific or higher or lower depending on whether the Exchange is a FFE–DE or SBE–FP–DE and the specific services HHS will provide, as outlined in the Federal agreement required under new proposed § 155.221(j)(2)(ii). We will continue to examine costs, enrollment, premium, and state transition estimates for the issuers offering QHPs on the Exchanges using the Federal platform for the 2022 benefit year as we finalize the FFE and SBE–FP user fee rates (including the proposed rates for the new proposed FFE–DE and SBE–FP–DE options for the 2023 benefit year). We seek comment on these proposals.

c. State User Fee Collection Administration (§ 156.50(c)(2))

We also propose to eliminate the state user fee collection flexibility that HHS had previously offered to states in the 2017 Payment Notice. We propose that HHS would not collect an additional user fee, if a state so requests, from issuers at a rate specified by the state to cover costs incurred by the state for the functions the state retains. HHS previously provided this flexibility to states in order to help reduce the administrative burden on states of collecting additional user fees. However, our subsequent internal analysis demonstrated that the process of collecting the state portion of the user fee and remitting it to the state, would increase the operational burden and cost incurred by HHS. Therefore, we are amending § 156.50(c)(2) to remove this alternate user fee collection mechanism. We note that this proposal does not change the ability of an SBE–FP to request that HHS collect from the SBE–FP state regulatory entity the total amount that would result from the percent of monthly premiums charged for enrollment through the federal platform, instead of HHS collecting the fee directly from SBE–FP issuers.

d. Eligibility for User Fee Adjustments for Issuers Participating Through SBE–FPs (§ 156.50(d))

We are proposing to amend § 156.50(d) to clarify that issuers participating through SBE–FPs are eligible to receive adjustments to their federal user fee amounts that reflect the value of contraceptive claims they have reimbursed to third-party administrators (TPAs) that have provided contraceptive coverage on behalf of an eligible employer. In the final rules ''Coverage of Certain Preventative Services Under the Affordable Care Act,'' [169] these relationships were established as a method of both providing contraceptives for women and accommodating the religious beliefs of employers. In the 2017 Payment Notice,[170] we allowed State Exchanges to enter into agreements to rely on the Federal platform for certain Exchange functions to enhance efficiency and coordination between the state and federal programs, and to leverage the systems established by the FFEs to perform certain Exchange functions. Although we recognized that issuers participating in these types of Exchanges were subject to a federal user fee, § 156.50(d) was not amended to reflect the SBE–FP Exchange model. As such, in this rule, we propose to amend § 156.50(d) to explicitly include the issuers offering QHPs through SBE–FPs. We also propose to make conforming changes throughout the regulation text at § 156.50(d) to reflect the user fees applicable to FFEs and SBEs that adopt the DE option, as further discussed elsewhere in this rulemaking.

We seek comment on these proposals.

e. Request for Comments on Alternatives to Exchange User Fees (§ 156.50)

In the 2021 Payment Notice proposed rule we solicited comment on whether to lower the user fee rates in the final rule and any information that might inform future changes to the user fee rate. One commenter questioned the basis of the user fee, stating that the Exchanges do not provide a special benefit to issuers. The commenter asserted that 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 all flow to consumers, and not the issuers who pay them.

While the 2021 Payment Notice comment solicitation focused on the rate of the user fee, we appreciate the commenter's concerns regarding the justification for the user fee. Even when government policies seem well established—HHS is in its seventh year applying the Exchange user fee to issuers—it is always helpful to periodically step back and reassess whether a particular policy is still an effective and proper approach, and whether there are better alternatives.

We recognize the Exchanges serve a public purpose defined by the PPACA to facilitate the purchase of QHPs, determine eligibility for insurance affordability programs, and assist in enforcing the individual and employer shared responsibility provisions. The Exchanges also provide special benefits to issuers, including regulatory services and sales services similar to the services provided by agents and brokers. Whether or not the current balance of funding sources is appropriate based on the portion of activities that support a public purpose compared to a special benefit to issuers presents an important question.

In addition, we recognize the application of the Exchange user fee raises important fairness questions regarding who ultimately pays the fee and how much they pay. Issuers directly pass Exchange user fees on to their enrollees in the form of higher premiums, which issuers specifically document in their rate filings to justify their rates. Therefore, the people who effectively pay the Exchange user fee are largely limited to (1) people who pay the full premium without the benefit of PTCs subsidies and (2) federal taxpayers who tend to fully fund the marginal increase in premiums due to the user fee for people who receive PTC subsidies. The fact that single risk pool regulations under 45 CFR 156.80(d)(1)(ii) require the index rate to be adjusted on a market-wide basis based on Exchange user fees means that enrollees who purchase coverage outside the Exchange from a QHP issuer must pay higher premiums to support the Exchange. In addition, we recognize average premiums vary substantially across states and rating regions—varying from a statewide average of $389 to $942 in 2019 [171]—which is largely due to variations in claims experience. As a result, the per enrollee user fee can vary substantially

[169] 78 FR 39870 (July 2, 2013); 80 FR 41318 (July 14, 2015).

[170] 81 FR 12203 at 12293 (March 8, 2016).

[171] ''Early 2020 Effectuated Enrollment Snapshot,'' July 23, 2020. Available at *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Early-2020-2019-Effectuated-Enrollment-Report.pdf.*

based on factors that are not related to the cost of operating the Exchanges.

Because the Exchange user fee is specifically included in premium as a component of the index rate under 45 CFR 156.80(d)(1)(ii), we also recognize the fee raises important fairness questions regarding the treatment of commissions for agents and brokers in the MLR calculation. As noted previously, the Exchange provides sales services similar to the services provided by agents and brokers. Yet the cost of these services are treated completely differently within the MLR calculation. Exchange sales services are considered part of the premium, which helps the issuer meet the MLR requirement. Conversely, agent and broker commissions are treated as administrative costs, which counts against the issuer meeting the MLR requirement. As a result, the user fee combined with the method for calculating the MLR may give the Exchange a competitive advantage over agents and brokers.

Recognizing these concerns with the Exchange user fee, we are considering and seek comment on both the appropriateness of an alternative revenue source and the type of an alternate revenue source to ensure Exchanges can cover the costs of the Exchange in an effective, appropriate, and fair manner. While these comments would not change the funding source of Exchange related functions in this rule, the comments submitted in response to this solicitation may be used for further proposals.

2. 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

In the 2021 Payment Notice, we amended § 156.111(d) and added paragraph (f) to 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).

At § 156.111(f), we also required states to identify which state-required benefits are not in addition to EHB and do not require defrayal in accordance with § 155.170, and provide the basis for the state's determination. Under this requirement, a state's submission must describe all benefits requirements under state mandates applicable to QHPs in the individual or small group market 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 all benefits requirements under state mandates that were imposed any time after December 31, 2011, applicable to the individual or small group market. The state's report is also required to describe whether any of the state benefit requirements in the report were amended or repealed after December 31, 2011. Information in the state's report is required to be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS.

We also finalized § 156.111(d)(2) to specify 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 which benefits are in addition to EHB for the state for the applicable plan year. HHS's identification of which benefits are in addition to EHB will become part of the definition of EHB for the applicable state for the applicable plan year.

In the 2021 Payment Notice, we finalized that the annual reporting of state-required benefits would begin in plan year 2021 and set a July 1, 2021 deadline for states to submit to HHS their first complete reporting package. We now propose July 1, 2022 as the deadline for states to submit to HHS the complete reporting package for the second year of reporting. This would mean that states would notify HHS in the manner specified by HHS by July 1, 2022, of any benefits in addition to EHB that QHPs are required to cover in plan year 2022 or after plan year 2022 by state action taken by May 2, 2022 (60 days prior to the annual submission deadline). As part of this reporting, states must also identify which state-required benefits are not in addition to EHB and do not require defrayal in accordance with § 155.170, and provide the basis for the state's determination, by the July 1, 2022 reporting submission deadline.

The first reporting cycle was intended to set the baseline list of state-required benefits applicable to QHPs in the individual and/or small group market. For each subsequent annual reporting cycle thereafter, the state is only 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. If a state has not imposed, amended, or repealed any state benefit requirements since the prior year's reporting deadline, 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, the state should submit the same reporting package as the previous reporting cycle and affirmatively indicate to HHS that there have been no changes.

b. States' EHB-Benchmark Plan Options

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.

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 propose May 6, 2022, as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2023 plan year. We emphasize 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 recommend states submit applications at least 30 days prior to the submission deadline to ensure completion of their documents by the proposed deadline. We also remind states that they must complete the required public comment period and submit a complete application by the deadline. We seek comment on the proposed deadline.

In the 2019 Payment Notice, we also finalized flexibility 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 also propose May 6, 2022, as the deadline for states to

notify HHS 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 seek comment on the proposed deadline.

3. Premium Adjustment Percentage (§ 156.130)(e))

We propose the 2022 benefit year 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 CMS' Office of the Actuary. For the 2022 benefit year, the premium adjustment percentage will represent the percentage by which this measure for 2021 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 three other 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 final rule [172] and 2015 Market Standards Rule [173] 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. The 2020 Payment Notice final rule [174] established that we will calculate the average per capita premium 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. Additionally, as finalized in the 2021 Payment Notice final rule,[175] we will finalize the premium adjustment percentage and related parameters for the 2022 benefit year using the NHEA data available at the time of this proposed rule for the 2022 benefit year.

As such, we propose that the premium adjustment percentage for 2022 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 2021 ($7,036) exceeds the most recent NHEA estimate of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 ($4,883).[176] Using this formula, the proposed premium adjustment percentage for the 2022 benefit year is 1.4409174688 ($7,036/$4,883), which represents an increase in private health insurance (excluding Medigap and property and casualty insurance) premiums of approximately 44.1 percent over the period from 2013 to 2021.

Based on the proposed 2022 premium adjustment percentage, we propose the following cost-sharing parameters for benefit year 2022.

a. Maximum Annual Limitation on Cost Sharing for Plan Year 2022

We propose to increase the maximum annual limitation on cost sharing for the 2022 benefit year based on the proposed value calculated for the premium adjustment percentage for the 2022 benefit year. As finalized in the EHB final rule [177] at § 156.130(a)(2), for the 2022 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 2022. 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 1.4409174688 for 2022 as proposed above, 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,[178] we propose that the 2022 benefit year maximum annual limitation on cost sharing would be $9,100 for self-only coverage and $18,200 for other than self-only coverage. This represents an approximately 6.4 percent increase above the 2021 parameters of $8,550 for self-only coverage and $17,100 for other than self-only coverage. We seek comment on these proposals.

b. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

We propose for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking, to use the reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations determined by the methodology we established beginning with the 2014 benefit year, as further described later in this section of the preamble.

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

[172] 79 FR 13743.

[173] 79 FR 30240.

[174] 84 FR 17454.

[175] See 85 FR 29228.

[176] The 2013 and 2021 per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) figures used for this calculation reflect the latest NHEA data. 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 2019–2028—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 available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.*

[177] See 78 FR 12847 through 12848.

[178] See Revenue Procedure 2013–25, 2013–21 IRB 1110. *http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.*

percent, or 94 percent, depending on the income of the enrollee).

As we propose above, the 2022 maximum annual limitation on cost sharing would be $9,100 for self-only coverage and $18,200 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. Below, we describe our analysis for the 2022 plan year and our proposed results.

Consistent with our analysis for the 2014 through 2021 benefit years' reduced maximum annual limitation on cost sharing, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the PPACA to the proposed estimated 2022 maximum annual limitation on cost sharing for self-only coverage ($9,100). The test plan designs are based on data collected for 2021 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 2022, the test silver level QHPs included a PPO with typical cost-sharing structure ($9,100 annual limitation on cost sharing, $2,775 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing ($7,400 annual limitation on cost sharing, $3,050 deductible, and 20 percent in-network coinsurance rate); and an HMO ($9,100 annual limitation on cost sharing, $4,800 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 a draft version of the 2022 benefit year AV Calculator [179] and observed how the reductions in the maximum annual limitation on cost sharing specified in the PPACA affected the AVs of the plans. As with prior years, 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).

However, as with prior years, we continue to find that 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. Furthermore, as with prior years, 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 would cause an increase in AV that exceeds the maximum 70 percent level in the statute.

Beginning with the 2023 benefit year, we are proposing to publish the required contribution percentage, along with the premium adjustment percentage and the annual cost-sharing limitation parameters, in guidance. For additional discussion of the provisions of this proposal, please see the preamble for Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130).

The calculation of the reduced maximum annual limitation on cost sharing has remained consistent since the 2014 Payment Notice due to year-over-year consistency of the results of our analysis regarding the effects of the reduced maximum annual limitation on cost sharing on the AV of silver plan variations. Therefore, as a result of the apparent stability of those results, and consistent with prior Payment Notices, we propose to continue to use the maximum annual limitation on cost sharing reductions of ⅔ for enrollees with a household income between 100 and 200 percent of FPL, ⅕ for enrollees with a household income between 200 and 250 percent of FPL, and no reduction for individuals with household incomes of 250 to 400 percent of FPL for the 2022 benefit year and beyond. We would continue to review the effects of these reductions annually, and should we determine that this approach should be changed to better reflect the statutorily specified AVs for silver plan variations, we would propose to change these reductions through notice and comment rulemaking.

Specifically, we propose to continue to use the methodology described above for analyzing the effects of the reduced maximum annual limitation on cost sharing on the AV of silver plan variations to verify that the reductions do not result in unacceptably high AVs before we publish these values in guidance for a given benefit year. Subsequently, if a future analysis using this methodology supports a modification to the reduced maximum annual limitation for any of the household income bands for a future benefit year, we would propose those modifications to the reduced maximum annual limitations through notice-and-comment rulemaking, as appropriate.

We note 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 result in the AV of the QHP meeting the specified level.

We seek comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing calculation methodology for the 2022 benefit year and beyond. We also seek comment on the proposed reduced annual limitations on cost sharing for the 2022 benefit year (Table 9).

We note that for 2022, as described in § 156.135(d), states are permitted to request HHS's approval for state-specific datasets for use as the standard population to calculate AV. No state submitted a dataset by the September 1, 2020 deadline.

[179] Available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.*

TABLE 9—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2022

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2020	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2020
Individuals eligible for CSRs under § 155.305(g)(2)(i) (100–150 percent of FPL)	$3,000	$6,000
Individuals eligible for CSRs under § 155.305(g)(2)(ii) (151–200 percent of FPL)	3,000	6,000
Individuals eligible for CSRs under § 155.305(g)(2)(iii) (201–250 percent of FPL)	7,250	14,500

c. Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130)

Since the 2014 benefit year, HHS has published the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing, and required contribution percentage parameters through notice-and-comment rulemaking. Beginning with the 2023 benefit year, we propose to publish these parameters in guidance by January of the year preceding the applicable benefit year, unless HHS is changing the methodology for calculating the parameters, in which case, we would do so through notice-and-comment rulemaking. We additionally propose to publish in guidance the premium adjustment percentage and related parameters using the most recent NHEA income and premium data that is available at the time these values are published in guidance or, if HHS is changing the methodology for calculating these parameters, at the time these values are proposed in notice-and-comment rulemaking. Publication of these parameters prior to the release of updates to the NHEA data, which typically (but not always) occurs in February or March, is consistent with the 2021 Payment Notice policy to finalize the premium adjustment percentage, maximum limitation on cost sharing, reduced maximum limitation on cost sharing, and required contribution percentage using NHEA data that would be available at the time that the proposed rule would have been published.

In the EHB final rule,[180] HHS established at § 156.130(e) that HHS will publish the annual premium adjustment percentage in the annual HHS notice of benefit and payment parameters. Additionally, in the 2014 Payment Notice final rule,[181] HHS established at § 156.420(a)(1)(i), (2)(i), and (3)(i), that the reduced annual limitations on cost sharing would be published in the applicable benefit year's annual HHS notice of benefit and payment parameters. Due to the timing of publication of the annual HHS notice of benefit and payment parameters final rule in past years, stakeholders have suggested that when HHS is not changing the calculation methodology for these parameters, HHS should publish earlier the premium adjustment percentage, maximum limitation on cost sharing, reduced maximum limitation on cost sharing, and required contribution percentage. These stakeholders assert that an earlier publication would allow issuers to incorporate these parameters for rate setting and the submission of QHP benefit templates earlier than would be possible if the parameters were published in the applicable benefit year's notice of benefit and payment parameters.

In addition, because the methodologies used to calculate the premium adjustment percentage, required contribution percentage, and maximum annual limitation on cost sharing have been previously established through rulemaking, the calculation of these amounts is a function of entering the applicable figures into the established equations, and therefore, does not require rulemaking to establish. Additionally, the calculation of the reduced maximum annual limitation on cost sharing has remained consistent since the 2014 Payment Notice final rule. Therefore, as discussed earlier in this proposed rule, we have proposed the reductions to the maximum annual limitation on cost sharing as well as the methodology for determining whether these reductions raise plan AVs above acceptable levels for the 2022 benefit year and beyond.

With these methodologies in place, beginning with the 2023 benefit year, we propose to amend §§ 156.130(e) and 156.420(a) to reflect that we would publish the premium adjustment percentage, along with the maximum annual limitation on cost sharing, the reduced maximum annual limitation on cost sharing, and the required contribution percentage in guidance by January of the year preceding the applicable benefit year (for example, the 2023 premium adjustment percentage would be published in guidance no later than January 2022), unless HHS is amending the methodology to calculate these parameters, in which case HHS would amend the methodology and publish the parameters through notice-and-comment rulemaking.

We believe that publishing the final premium adjustment percentage and associated final parameters in guidance annually instead of through notice-and-comment rulemaking is consistent with our efforts to provide information to stakeholders in a timely manner.

We seek comment on these proposals.

4. Network Adequacy Standards (§ 156.230)

45 CFR 156.230, which implements section 1311(c)(1)(B) of the PPACA, describes the network adequacy standards for QHP issuers that use a provider network. We have received questions regarding whether the requirements at § 156.230 apply to a plan that does not use a provider network, such as an indemnity plan, and does not vary benefits based on whether enrollees receive services from an in-network or out-of-network provider.

Nothing in the PPACA requires a QHP issuer to use a provider network. Accordingly, a QHP issuer may choose to design a QHP that does not use a provider network, and to provide equal benefits for covered services without regard to whether the issuer has a network participation agreement with the provider that furnishes the covered services. Section 156.230 does not impose any network adequacy certification requirement for QHPs that do not use a provider network, and has not since the inception of the Exchanges. To address any ambiguity in this section, we propose to codify this

[180] 78 FR 12834 through 12833.

[181] 78 FR 15409.

longstanding interpretation at paragraph (f) to provide that a plan that does not vary benefits based on whether the issuer has a network participation agreement with the provider that furnishes the covered services toned not comply with the network adequacy standards at paragraphs (a) through (e) in order to be certified as a QHP. This proposal would simply clarify existing QHP requirements and would not change or add any additional QHP certification requirement.

We invite comment on this proposal.

5. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

In the 2021 Payment Notice, CMS finalized a requirement that under § 156.270(b)(1), QHP issuers must send termination notices with effective dates and reason for the termination to enrollees for all termination events. We finalized this as proposed, noting that all commenters who weighed in on this topic supported our proposal. This policy became effective July 13, 2020. We are not proposing any changes to paragraph (b)(1) beyond what we finalized in the 2021 Payment Notice for the reasons discussed below.

In finalizing this rule, CMS inadvertently omitted discussion of two comments opposing the proposal. These comments raised concerns about unnecessary additional administrative costs and IT builds, and noted that a termination notice could be confusing in certain scenarios—for example, if the enrollee switches between QHPs offered by the same issuer, a termination notice from their issuer could cause confusion. These commenters proposed instead that Exchanges should be required to clearly convey the eligibility termination reason and effective date in the Exchange's own eligibility notices, consistent with the data conveyed to issuers on 834 termination transactions.

We are sensitive to commenters' concerns that issuers need sufficient time to build IT systems to implement this policy. In response, CMS issued guidance allowing issuers using the federal platform enforcement discretion until February 1, 2021 to implement the new termination notice requirement.[182]

However, the comments in opposition of the proposal do not change CMS's policy goals underlying our decision to finalize the rule as proposed. FFEs do not send termination notices for any termination scenario other than citizenship data-matching issue expirations and terminations associated with Medicare PDM when the enrollee has elected at plan selection to terminate Exchange coverage when found dually enrolled. The FFEs also do not send termination notices in enrollee-initiated terminations which must be requested at the Exchange. Similarly, the FFEs do not send termination notices when an enrollee switches QHPs within the same issuer. This is all appropriate, because the issuer is the primary communicator to the enrollee about their coverage. We still believe that termination notices would be helpful in these scenarios, even in plan selection changes, because an enrollee switching QHPs could have their premium, cost sharing, and provider network affected. As one of the comments in support of our proposal noted, 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. Another commenter agreed that issuers should send termination notices during voluntary terminations associated with Medicare PDM as it would help the enrollee confidently transition to Medicare.

Complaints about terminations are one of the largest sources of casework. More consistent communication is part of the solution. We believe consumers should be notified of these changes, even if they initiated them so that enrollees have a record that the issuer completed the request. Issuers are the proper messenger of termination noticing for many reasons. For example, Exchange issuers historically are the senders of termination notices, and some issuers acknowledge in their comments that they already do send termination notices in all scenarios. Furthermore, the issuer has record of the termination date needed for the termination notice before the Exchange in some cases, such as some retroactive termination requests handled through casework, and State Exchange issuer terminations described in § 155.430(d)(iv). Indeed, one reason we proposed regulating in this area is that we were receiving detailed questions from issuers about which termination scenarios required issuer notices; we believe requiring issuer termination notices for all scenarios in the long run makes the requirement simpler.

Therefore, we are not proposing any changes to § 156.270(b)(1) beyond what we finalized in the 2021 Payment Notice.

6. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295)

Section 6005 of the PPACA added section 1150A(a)(2) of the Act to require a PBM under a contract with a Medicare Part D plan sponsor or Medicare Advantage plan that offers a Medicare Part D plan, or with a QHP offered through an Exchange established by a state under section 1311 of the PPACA[183] to provide certain prescription drug information to the Secretary, at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer or their PBM must report.[184] Section 1150A(c) of the Act requires the information reported to be kept confidential and not to be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.[185]

In the 2012 Exchange Final Rule, we codified the requirements contained in section 1150A of the Act with regard to QHPs at § 156.295. In that rule, we interpreted section 1150A of the Act to require QHP issuers to report the information described in section

[182] "Enforcement Safe Harbor for Qualified Health Plan Termination Notices During the 2019 Benefit Year," August 26, 2020. Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Termination-Notices-Enforcement-Discretion.pdf.*

[183] This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the PPACA. *King* v. *Burwell,* 576 U.S. 988 (2015).

[184] This information is: The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract; the aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed; and, the aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

[185] The purposes are: As the Secretary determines to be necessary to carry out Section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the PPACA.

1150A(b) of the Act and did not specify the responsibilities of PBMs that contract with QHP issuers to report this information. On January 28, 2020 [186] and on September 11, 2020,[187] we published notices in the **Federal Register** and solicited public comment on collection of information requirements detailing the proposed collection envisioned by section 1150A of the Act to HHS.[188]

a. QHP Issuer Responsibilities

Elsewhere in this rule, we propose to add new part 184 to address the responsibilities of PBMs under the PPACA and to add § 184.50 to codify in regulation the statutory requirement that PBMs that are under contract with an issuer of one or more QHPs report the data required by section 1150A of the Act. Accordingly, we propose to revise § 156.295(a) to state that where a QHP issuer does not contract with a PBM to administer the prescription drug benefit for QHPs, the QHP issuer will report the data required by section 1150A of the Act to HHS. We propose corresponding revisions throughout § 156.295 to remove the applicability of the reporting requirement for PBMs under this section and propose revising the title to ''Prescription drug distribution and cost reporting by QHP issuers''.

As explained in the preamble at § 184.50, we acknowledge that section 1150A places responsibility on both the QHP issuer and their PBMs to report this prescription drug data. Generally, where a QHP issuer contracts with a PBM, the PBM is more likely to be the source of the data that must be reported. Therefore, to reduce overall burden, rather than requiring the QHP issuer to serve as a conduit between its PBM and HHS, or unnecessarily requiring both the PBM and the QHP issuer to submit duplicated data, we propose to implement section 1150A to make QHP issuers responsible for reporting this data directly to the Secretary only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Where a QHP contracts with a PBM, the PBM is responsible for reporting data to the Secretary as required by § 184.50.

Although we are unaware of any QHP issuer that does not currently utilize a PBM, we believe that, together, the proposals to revise § 156.295 and to add § 184.50 would ensure the collection of data required by section 1150A of the Act in all circumstances, including when a QHP issuer does not use a PBM to administer its prescription drug benefit. Retaining the requirement for QHP issuers to report data at § 156.295 when they do not contract with a PBM would ensure that the data is consistently collected every plan year.

We also propose to remove § 156.295(a)(3) to remove the requirement for QHP issuers to report spread pricing amounts when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Spread pricing amounts are only present where a PBM acts as an intermediary between the QHP issuer and a drug manufacturer. If a QHP issuer does not contract with a PBM, no such intermediary exists and it is not possible for QHP issuers to report this data.

We seek comment on these proposals.

b. Reporting of Data by Pharmacy Type

Section 1150A(b)(1) of the Act requires the Secretary to collect certain QHP prescription drug data [189] by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public). This requirement was previously codified at § 156.295(a)(1). In the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes final rule, we recognized that it is not currently possible to report such data by pharmacy type because pharmacy type is not a standard classification currently captured in industry databases or files.[190] We understand that these types continue not to be standard classifications currently captured in industry databases or files, as indicated by comments submitted in response to the January 28, 2020 notice in the **Federal Register** soliciting public comment on the collection of information requirements of this collection.[191] To reduce the burden of this collection, we propose to revise § 156.295(a)(1) to remove the requirement to report the data described at section 1150A(b)(1) of the Act by pharmacy type. We intend to collect this information at a time when this requirement would impose reasonable burden. We seek comment on ways that we may collect the data by pharmacy type without creating unreasonable burden and any existing definitions that may exist that could be leveraged for this purpose. We also seek comment on the time and costs required for PBMs to begin reporting by pharmacy type, if definitions were finalized.

7. Oversight of the Administration of the Advance Payments of the Premium Tax Credit, Cost-Sharing Reductions, and User Fee Programs (§ 156.480)

a. Application of Requirements to Issuers in State Exchanges and SBE–FPs

In the second Program Integrity Rule, we finalized general provisions related to the oversight of QHP issuers in relation to APTC and CSRs.[192] We explained that since APTC and CSR payments are federal funds which pass from HHS directly to QHP issuers, it is necessary for HHS to oversee QHP issuer compliance in these areas, regardless of whether the QHP is offered through a State Exchange or an FFE. As such, to effectively oversee the payment of APTC and CSRs by QHP issuers, HHS established standards in part 156, subpart E for QHP issuers participating in FFEs and State Exchanges. We also noted that in states with State Exchanges, the state would have primary enforcement authority over QHP issuers participating in the state's individual market exchange that were not in compliance with the standards set forth in part 156, subpart E.[193] However, if the State Exchange does not enforce such standards, HHS would enforce compliance with these requirements, including the imposition of CMPs on QHP issuers participating in State Exchanges using the same standards and processes for QHP issuers participating in FFEs set forth in part 156, subpart I.[194] In the second Program Integrity Rule, we also finalized general provisions that require issuers offering QHPs in an FFE maintain all documents and records and other evidence of accounting procedures and practices, which are critical for HHS to conduct activities necessary to safeguard the financial and programmatic integrity of the FFEs.[195] As finalized in 45 CFR 156.705(a)(1), this includes the authority for HHS to include periodic auditing of the QHP issuer's financial records related to the participation in an FFE. To date, we have leveraged this

[186] 85 FR 4993 through 4994.

[187] 85 FR 56227 through 56229.

[188] Pharmacy Benefit Manager Transparency. CMS–10725. Available at *https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10725.*

[189] Section 1150A(b)(1) requires the reporting of the percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed.

[190] See 77 FR 22072 at 22093.

[191] See 85 FR 4993 through 4994.

[192] See 78 FR 65077 and 65078.

[193] See the proposed Program Integrity Rule, 78 FR 37058. Also see 78 FR at 65077 and 65078.

[194] Ibid.

[195] See 78 FR 65078 and 65079.

authority to conduct user fee audits of QHP issuers participating in an FFE.

In this rulemaking, we propose amendments to consolidate HHS audit authority regarding APTC, CSR, and user fee audits by expanding the audit authority under § 156.480(c) to also capture user fees audits by HHS, or its designee, of QHP issuers participating in an FFE. Additionally, as part of determining whether APTC and CSR amounts were properly paid to issuers, and whether user fee amounts were properly collected, HHS regularly identifies discrepancies in issuer records caused by issuer non-compliance with other applicable Exchange operational standards. Examples include failure to correctly effectuate or terminate coverage, or to correctly calculate premiums. In addition, we propose to apply the same framework to QHP issuers participating in SBE–FP states. As such, QHP issuers in SBE–FP states would be required to comply with HHS audits under § 156.480(c) to confirm compliance with the applicable standards established in part 156, subpart E for APTC and CSRs and § 156.50 for user fees.

We further propose that in situations where the state fails to substantially enforce such standards, HHS would enforce compliance, including imposing CMPs using the same standards set forth in part 156, subpart I. Based on our experience conducting audits of APTC, CSRs, and user fees, we also propose several amendments to § 156.480(c) to ensure we can effectively oversee the payment of these amounts by QHP issuers, regardless of Exchange type (for example, FFE, State Exchange, or SBE–FP).

As detailed below, to further support our program integrity efforts in these areas, we propose to amend § 156.480(c) to codify additional details regarding HHS audits and to capture authority for HHS to conduct compliance reviews of QHP issuer compliance with the applicable Federal APTC, CSR, and user fee standards,[196] including the consequences for the failure to comply with an audit. In addition, we propose amendments to §§ 156.800 and 156.805 to set forth the framework for HHS enforcement of the applicable Federal APTC, CSR, and user fee standards in situations where state authorities fail to substantially enforce those standards with respect to the QHP issuers participating in State Exchanges and SBE–FPs.

We seek comment on these proposals, including with respect to how HHS could coordinate with State Exchanges, SBE–FPs, and state authorities to address non-compliance by QHP issuers with applicable Federal APTC, CSRs, and user fee standards. We seek comment on ways to balance enforcement by State Exchanges and SBE–FPs and the protection and oversight of federal funds by HHS.

b. Audits and Compliance Reviews of APTC, CSRs, and User Fees (§ 156.480(c))

In prior rulemaking, we codified authority for HHS to audit an issuer that offers a QHP in the individual market through an Exchange to assess compliance with the requirements of part 156, subpart E.[197] We also previously codified general authority for HHS to periodically audit a QHP issuer's financial records related to its participation in an FFE.[198] Recently, HHS completed the audits for the 2014 benefit year CSR payments. During these audits, HHS encountered challenges working with some issuers. Specifically, HHS experienced difficulties receiving requested audit data and materials in a timely fashion and receiving data in a format that is readily usable for purposes of conducting the audit. As such, similar to the proposals related to audits of issuers of reinsurance-eligible plans and risk adjustment covered plans discussed earlier in this proposed rule, we propose to amend § 156.480(c) to provide more clarity around the issuer requirements for APTC and CSR audits. The proposed amendments codify more details about the audit process and clarify issuer obligations with respect to these audits, including what it means to comply with an audit and the consequences for failing to comply with such requirements. Additionally, we propose to amend § 156.480(c) to also capture and clarify HHS's ability to audit FFE and SBE–FP user fees. As such we proposed to rename § 156.480, ''Oversight of the Administration of the Advance Payments of the Premium Tax Credit, Cost-sharing Reductions, and User Fee Programs.'' HHS currently reviews compliance with applicable Federal user fee standards when conducting APTC audits because the same data is used for both purposes; as such, there will be minimal increased burden as a result from this codification.

We also propose several amendments to § 156.480(c) to expand the oversight tools available to HHS beyond traditional audits to also provide authority for HHS to conduct compliance reviews of QHP issuers to assess compliance with the applicable Federal APTC, CSR, and user fee standards. These proposed HHS compliance reviews would follow the standards set forth for compliance review of QHP issuers participating in FFEs established in 45 CFR 156.715. However, compliance reviews under this section would be conducted to confirm QHP issuer compliance with the APTC, CSR, and user fee standards in subpart E of part 156 and 45 CFR 156.50 for user fees, as applicable, and they would generally extend to QHP issuers participating in all Exchanges.[199] A compliance review may be targeted at a specific potential error and conducted on an ad hoc basis.[200] For example, HHS may require an issuer to submit data pertaining to specific data submissions. We believe this flexibility is necessary and appropriate to provide HHS a mechanism to address situations in which a systematic error or issue is identified during the random and targeted auditing of a sample of QHP issuers, and HHS suspects similarly situated issuers may have experienced the same systematic error or issue but were not selected for audit in the year in question. We intend to continue our collaborative oversight approach and coordinate with State Exchanges and SBE–FPs to ensure QHP issuer compliance with the applicable standards in part 156, subpart E and 45 CFR 156.50.

First, we propose to rename § 156.480(c) to ''Audits and Compliance Reviews'' in order to clarify that the authority described in this section would apply to audits and the proposed HHS compliance reviews to evaluate QHP issuer compliance with the applicable Federal APTC, CSR, and user fee standards. We similarly propose to update the introductory language in § 156.480(c) to incorporate a reference to HHS compliance reviews. As amended, § 156.480(c) would provide that HHS or its designee may audit and perform compliance reviews to assess whether an issuer that offers a QHP in the individual market through an Exchange is in compliance with the applicable

[196] The applicable Federal standards for APTC and CSRs are found in part 156, subpart E, which apply to QHP issuers participating in all Exchanges types (FFEs, State Exchanges and SBE–FPs). The applicable Federal standards for user fees are found in 45 CFR 156.50, which apply to QHP issuers in FFEs and SBE–FPs.

[197] 78 FR 65077 and 65078.

[198] See 45 CFR 156.705(a)(1). Also see 78 FR 65078 and 65079.

[199] HHS does not intend to conduct user fee compliance reviews of QHP issuers participating in State Exchanges that do not rely on the Federal platform. Such reviews would be limited to QHP issuers participating in FFE and SBE–FP states.

[200] See 78 FR 65100.

requirements of subpart E, part 156, and 45 CFR 156.50. We propose to capture in a new sentence in the amended § 156.480(c) that HHS would conduct these compliance reviews consistent with the standards set forth in 45 CFR 156.715. As detailed earlier in this preamble, these oversight tools would be available to HHS to evaluate compliance by QHP issuers participating in all Exchanges with the applicable Federal APTC, CSR, and user fee standards.

Second, we propose to add new § 156.480(c)(1) to establish notice and conference requirements for these audits. Proposed new paragraph (c)(1) states that HHS would provide at least 15 calendar days advance notice of its intent to conduct an audit of an QHP issuer under § 156.480(c). Under proposed paragraph (c)(1)(i), HHS proposes to codify that all audits would include an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Third, HHS proposes to add new paragraph (c)(2) to capture the requirements issuers must meet to comply with an audit under this section. Under the proposed paragraph (c)(2)(i), we propose to require the issuer to ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section. In new proposed paragraph (c)(2)(ii), we propose to require issuers to submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial deadline communicated and established by HHS at the entrance conference described in proposed paragraph (c)(1)(i). For example, for CSR audits, HHS may request that QHP issuers provide a re-adjudicated claims data extract for the selected sample of policies to verify accuracy of the re-adjudication process and reported amounts (this would include verification of all elements necessary to perform accurate re-adjudication) and data extract containing incurred claims for the selected sample of policies to verify accuracy of actual amount the enrollee(s) paid for EHBs via an Electronic File Transfer. As another example, for APTC audits, issuers may be asked to provide data to validate and support APTC payments received for the applicable benefit year.

Fourth, under proposed § 156.480(c)(2)(iii), HHS proposes to require that issuers respond to any audit notices, letters, and inquires, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the notice, letter, request, or inquiry. We believe that the proposed requirements in paragraph (c)(2) are necessary and appropriate to ensure the timely completion of audits and to protect the integrity of the APTC, CSR, and user fee programs and the payments made thereunder.

Fifth, recognizing that there may be situations that warrant an extension of the timeframes under paragraph (c)(2)(ii) or (iii), as applicable, we propose to also add a new paragraph (c)(2)(iv) to establish a process for an issuer to request an extension. To request an extension, we propose to require the issuer to submit a written request to HHS within the applicable timeframe established in paragraph (c)(2)(ii) or (iii). The written request would have to detail the reasons for the extension request and the good cause in support of the request. For example, good cause may include an inability to produce information in light of unforeseen emergencies, natural disasters, or a lack of resources due to a PHE. If the extension is granted, the issuer must respond within the timeframe specified in HHS' notice granting the extension of time.

Sixth, under § 156.480(c)(3), HHS proposes that it would share its preliminary audit findings with the issuer, and further proposes that the issuer would then have 30 calendar days to respond to such findings in the format and manner as specified by HHS. HHS would describe the process, format, and manner by which an issuer can dispute the preliminary audit findings in the preliminary audit report sent to the issuer. For example, if the issuer disagrees with the findings set forth in the preliminary audit report, HHS would require the issuer to respond to such findings by submitting written explanations that detail its dispute(s) or additional rebuttal information via Electronic File Transfer. HHS proposes under paragraph (c)(3)(i) that if the issuer does not dispute or otherwise respond to the preliminary findings within 30 calendar days, the audit findings would become final. In new proposed paragraph (c)(3)(ii), if the issuer timely responds and disputes the preliminary audit findings within 30 calendar days, HHS would review and consider such response and finalize the audit findings after such review. HHS would provide contact and other information necessary for an issuer to respond to the preliminary audit findings in the preliminary audit report sent to the issuer.

Seventh, HHS proposes to add a new section at § 156.480(c)(4) to capture the process and requirements related to final audit findings and reports. If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS. We note that the actions set forth in the final audit report could require an issuer to return APTC or CSRs or make additional user fee payments. HHS further proposes that (1) the issuer must provide a written corrective action plan to HHS for approval within 30 calendar days of the issuance of the final audit report; (2) the issuer must implement the corrective action plan; and (3) the issuer must provide HHS with written documentation demonstrating the adoption and completion of the required corrective actions.

If an issuer fails to comply with the audit requirements set forth in new proposed § 156.480(c), HHS proposes in paragraph (c)(5)(i) that HHS would notify the issuer of payments received that the issuer has not adequately substantiated, and in new proposed paragraph (c)(5)(ii), HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated if the APTC, CSR, or user fee debt is not paid. Therefore, the continued failure to respond to or cooperate with an audit under paragraph (c) and provide the necessary information to substantiate the payments made could result in HHS recouping up to 100 percent of the APTC or CSR payments made to an issuer for the benefit year(s) that are the subject of the audit if the APTC,CSR, or user fee debt is not paid.

APTC and CSR amounts recovered by HHS as a result of an audit under § 156.480(c) would be paid to the U.S. Treasury. User fee amounts recovered by HHS as a result of an audit under paragraph (c) would be paid to the ACA Marketplace user fee program collection account.

Lastly, HHS proposes to add a new paragraph (c)(6) to § 156.480 to codify HHS' ability to enforce the applicable Federal APTC, CSR, and user fee standards if a State Exchange or SBE–FP is not enforcing or fails to substantially enforce one or more of these requirements. In instances where HHS enforces compliance with the applicable APTC, CSR, and user fee standards with respect to QHP issuers participating in State Exchanges or SBE–FPs, HHS would use the same standards and processes as outlined in §§ 156.805 and

156.806 for QHP issuers participating in an FFE with respect to the imposition of CMPs. This would include the proposed extension of the process outlined in § 156.901, *et seq.* for the QHP issuer to appeal the imposition of CMPs. For a discussion of the framework and proposed accompanying penalties for non-compliance in situations where HHS is responsible for enforcement of these requirements, see the below discussion of proposed changes to §§ 156.800 and § 156.805.

We seek comment on these proposals, including HHS's clarification of its compliance review authority, the proposed timeframes and processes for issuers to respond to audit notices and requests for information and for issuers to request extensions of those timeframes, and the proposals related to HHS's authority to enforce compliance with the above requirements if a State Exchange or SBE–FP is not enforcing or fails to substantially enforce one or more of these requirements.

8. Subpart I—Enforcement Remedies in Federally-Facilitated Exchanges; Available Remedies Scope (§ 156.800)

In this proposed rule, we propose to rename Subpart I to ''Enforcement Remedies in the Exchanges,'' and to make other amendments to clarify that HHS has the ability to impose CMPs when it is enforcing the applicable federal requirements in part 156, subpart E and 45 CFR 156.50 for user fees, regardless of whether the Exchange is established and operated by a state (including a regional Exchange or subsidiary exchange) or by HHS.[201] As explained in prior rulemaking, in states where there is a State Exchange or SBE–FP, the State Exchange or SBE–FP has primary enforcement authority over QHP issuers participating in the Exchange and ensuring compliance with the applicable Federal APTC, CSR, and user fee standards.[202] However, consistent with the framework established in section 1321(c)(2) of the PPACA, HHS has authority to step in to enforce requirements related to the operation of Exchanges and the offering of QHPs through Exchanges if a state fails to do so.[203] [204] As such, in the case of a determination by the Secretary that a State Exchange or SBE–FP has failed to enforce or substantially enforce a federal requirement (or requirements) related to QHP issuer participation in the individual market Exchange, HHS has authority to step in and enforce QHP issuer compliance with the requirement(s).

Through its cross-reference to section 2723(b) of PHS Act, section 1321(c)(2) of the PPACA authorizes the Secretary to impose CMPs for non-compliance with applicable federal Exchange requirements. In this proposed rule, we propose to codify HHS authority to impose CMPs for non-compliance by QHP issuers that participate or have participated in a State Exchange or SBE–FP in situations where HHS steps in to enforce certain requirements. Specifically, this proposal is focused on ensuring compliance with the standards for APTC, CSR payments, and user fees captured in part 156, subpart E and 45 CFR 156.50. Under this proposal, we would apply the bases and follow the processes for imposing CMPs as set forth in § 156.805, would send a notice of non-compliance as set forth in § 156.806, and would extend the administrative review and appeal process set forth in § 156.901, *et seq.* to provide a forum for QHP issuers in State Exchanges and SBE–FPs to appeal the imposition of CMPs by HHS. We are not proposing to extend the authority to decertify a QHP under § 156.800(a)(2) for non-compliance by QHP issuers in State Exchanges or SBE–FPs; QHP de-certification in State Exchanges or SBE–FPs would remain an available enforcement tool for the applicable Exchange. This proposal is not intended to duplicate state enforcement efforts, as HHS generally depends on State Exchanges and SBE–FPs to enforce federal requirements applicable to QHPs and QHP issuers participating in the state's individual market Exchange. The proposed amendments are instead intended to establish an enforcement framework to capture situations where HHS is responsible for enforcement if a State Exchange or SBE–FP fails to do so and is focused on the Federal APTC, CSR, and user fee requirements in order to protect federal funds.

We expect that states that established a State Exchange or SBE–FP will enforce all applicable federal requirements applicable to QHPs and QHP issuers participating in Exchanges, including the applicable APTC, CSR, and user fee standards captured in part 156, subpart E and 45 CFR 156.50. However, to address situations where a State Exchange or SBE–FP fails to enforce these federal Exchange requirements, consistent with the framework established in section 2723(b) of the PHS Act, we propose that if HHS determines that a State Exchange or SBE–FP lacks authority or has otherwise failed to substantially enforce the requirements captured in part 156, subpart E or 45 CFR 156.50, HHS would step in to enforce these requirements with respect to QHP issuers participating in the State Exchange or SBE–FP. Once this determination is made, HHS would become responsible for enforcement and would take appropriate action to ensure QHP issuer compliance with the applicable requirement(s),[205] and may impose CMPs, if appropriate. To more clearly capture HHS's authority to impose CMPs in these situations, we proposed to amend the introductory sentence to § 156.800(a) to replace the current references to the ''Federally-facilitated Exchange'' with references to ''an Exchange.'' We also propose to amend § 156.800(b) to remove the word ''only'' from the sentence describing the scope of HHS sanctions with respect to QHP issuers participating in FFEs and to add a new second sentence that affirms HHS authority to impose CMPs for non-compliance with the applicable requirements in part 156, subpart E and 45 CFR 156.50 by QHP issuers participating in State Exchanges and SBE–FPs.

We intend to continue our collaborative enforcement approach and would coordinate our actions with state efforts to avoid duplication and to streamline oversight of the administration of APTC, CSRs, and user fees. We solicit comments for how HHS can collaborate with State Exchanges, SBE–FPs, and state authorities to proactively address non-compliance with applicable federal requirements and share compliance tools regarding CSRs, APTC and user fees.

9. Bases and Process for Imposing Civil Money Penalties in Federally-Facilitated Exchanges (§ 156.805)

We also propose to amend § 156.805 to more clearly reflect HHS's authority to impose CMPs due to non-compliance with respect to the applicable Federal APTC, CSR, and user fee standards against a QHP issuer participating in a State Exchange or SBE–FP. Under this proposal, we would use the same bases and process currently captured in

[201] Exchange models include State Exchanges, SBE–FPs, and FFEs. HHS does not intend to use this authority to impose CMPs related to user fee standards applicable to QHP issuer participating in State Exchanges.

[202] See the proposed Program Integrity Rule, 78 FR 37058. Also see 78 FR 65077 and 65078.

[203] Ibid.

[204] Section 1321(c)(2) of the PPACA provides that the enforcement framework established in section 2736(b), which was renumbered 2723(b), of the PHS Act shall apply to the enforcement of requirements established in section 1321(a)(1).

[205] As detailed earlier, when HHS is responsible for enforcement of these Exchange requirements, we also propose to extend authority for HHS to pursue a compliance review under §§ 156.480(c) and 156.715 to evaluate compliance with federal APTC, CSR, and user fee requirements by a QHP issuer participating in a State Exchange or SBE–FP.

§ 156.805 for imposing CMPs on QHP issuers participating in an FFE. More specifically, in § 156.805, we propose renaming this section to ''Bases and process for imposing CMPs in the Exchanges,'' and also propose to amend the introductory language in § 156.805(a) to use the words ''an Exchange,'' instead of ''Federally-facilitated Exchange,'' to more clearly capture HHS's authority to impose CMPs on QHP issuers participating in State Exchanges and SBE–FPs who fail to comply with the applicable requirements in part 156, subpart E or § 156.50 in situations where HHS is responsible for enforcement. We similarly propose to modify § 156.805(a)(5)(i) where the reference to ''HHS'' currently appears to also incorporate a reference to ''an Exchange'' to clarify that all QHP issuers must avoid intentionally or recklessly misrepresenting or falsifying APTC, CSR, and user fee information to both HHS and Exchanges, regardless of whether HHS or a state operates the Exchange. We propose this amendment to clarify that HHS has authority to impose CMPs against QHP issuers participating in State Exchanges and SBE–FPs who misrepresent or falsify APTC, CSR, and user fee information provided to HHS in situations where HHS is responsible for enforcement of the requirements in part 156, subpart E or § 156.50, including when HHS is performing an audit or compliance review under § 156.480(c). If HHS seeks to use this authority to impose CMPs against a QHP issuer participating in a State Exchange or SBE–FP, we propose the issuer would have the opportunity to appeal the CMPs following the existing framework for administrative hearings in § 156.901, *et seq*.

Finally, we propose to add a new paragraph (f) to § 156.805 to capture in this regulation details on the circumstances requiring HHS enforcement of the applicable requirements in part 156, subpart E and § 156.50. Consistent with the framework established in section 2723 of the PHS Act and section 1321(c) of the PPACA, we propose in new § 156.805(f)(1) that HHS's authority to enforce in these situations would be limited to situations where the State Exchange or SBE–FP notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201, *et seq*. that a State Exchange or SBE–FP is failing to substantially enforce these requirements.[206] In new proposed § 156.805(f)(2), we affirm that when HHS is responsible for enforcement in these circumstances, HHS may impose CMPs on an issuer in the State Exchange or SBE–FP, in accordance with the bases and process set forth in this section. As noted above, this includes the ability for a QHP issuer in a State Exchange or SBE–FP to appeal the imposition of CMPs by HHS following the existing framework for administrative hearings in § 156.901, *et seq.*

We propose that HHS would apply the same process HHS uses to determine when a state is failing to substantially enforce PHS Act requirements in determining whether a State Exchange or SBE–FP is substantially enforcing the applicable Federal APTC, CSR, and user fee standards. More specifically, we propose that if an audit of a QHP issuer in a State Exchange or SBE–FP demonstrates the State Exchange or SBE–FP's failure to enforce the applicable Federal APTC, CSR, and user fee standards, HHS would investigate the State Exchange or SBE–FP's enforcement and follow the process set forth in 45 CFR 150.207 if necessary. We propose that if HHS receives or obtains information (including information discovered through an audit) that a State Exchange or SBE–FP may not be enforcing the applicable requirements in part 156, subpart E, or § 156.50, HHS may initiate the process described in 45 CFR 150.207 to determine whether the State Exchange or SBE–FP is failing to substantially enforce these requirements. Mirroring the process set forth in 45 CFR 150.207 for making determinations regarding substantial enforcement of PHS Act requirements, HHS would follow the procedures in §§ 150.209 through 150.219 to determine if a State Exchange or SBE–FP is failing to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50. If HHS believes there is a reasonable question whether there has been a failure to enforce one or more of the applicable requirements in part 156, subpart E or 45 CFR 156.50, HHS would send a notice, as described in 45 CFR 150.213, identifying the applicable requirement(s) that allegedly have not been substantially enforced to the proper State Exchange or SBE–FP officials using the process outlined in 45 CFR 150.211. We propose that, following the process described in 45 CFR 150.215, HHS may extend, for good cause, the time the State Exchange or SBE–FP has for responding to the notice, such as if there is an agreement between HHS and the State Exchange or SBE–FP that there should be a public hearing on the State Exchange or SBE–FP's enforcement, or evidence that the State Exchange or SBE–FP is undertaking expedited enforcement activities. Using the process described in 45 CFR 150.217, if at the end of the extension period HHS determines that the State Exchange or SBE–FP has not established to HHS's satisfaction that it is enforcing the applicable requirement(s), we propose that HHS would consult with the appropriate State Exchange or SBE–FP officials, notify the State Exchange or SBE–FP of its preliminary determination that the State Exchange or SBE–FP has failed to substantially enforce the requirement(s) and that the failure is continuing, and permit the State Exchange or SBE–FP a reasonable opportunity to show evidence of substantial enforcement. If, after providing notice and a reasonable opportunity for the State Exchange or SBE–FP to show that it has corrected any failure to substantially enforce, HHS finds that the failure to substantially enforce has not been corrected, HHS would notify the State Exchange or SBE–FP of its final determination using the process described in 45 CFR 150.219. Therefore, we propose that after a determination that a State Exchange or SBE–FP is not or cannot substantially enforce the applicable requirements in part 156, subpart E or § 156.50, HHS could impose CMPs on issuers in the State Exchange or SBE–FP if there is cause for such imposition. HHS would also provide a notice of non-compliance, consistent with § 156.806, to QHP issuers in State Exchanges or SBE–FPs prior to imposing CMPs.

We seek to work collaboratively with State Exchanges, SBE–FPs, and state authorities for any topics of mutual concern and oversight activities where possible. We also seek comment to this proposal and ways in which HHS and state authorities can efficiently and effectively enforce federal standards related to APTC, CSRs, and user fees.

We also propose that if the changes made to the above § 156.800 and to § 156.805 are finalized as proposed, we would also apply § 156.903 such that an administrative law judge's authority also extends to CMPs imposed against QHP issuers in State Exchanges and SBE–FPs under § 156.805. Specifically, we propose to amend § 156.903(a) to extend the authority to State Exchanges and SBE–FPs so that the ALJ has the authority, including all the authority conferred by the Administrative Procedure Act, to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and

[206] See, for example, 45 CFR 150.203.

to issue an initial decision concerning the imposition of a CMP on a QHP offered in a FFE, State Exchange, or SBE–FP.

10. Subpart J—Administrative Review of QHP Issuer Sanctions (§§ 156.901, 156.927, 156.931, 156.947)

We propose to change the title to subpart J, removing the reference to ''in Federally-Facilitated Exchanges'' to make clear it applies to QHPs participating in any Exchange type to align with accompanying proposed changes outlined above to §§ 156.800 and 156.805. We also propose several procedural changes to provisions in subpart J of part 156 related to administrative hearings consistent with the amendments discussed in the preamble to part 150. These proposed changes are intended to align with the Departmental Appeals Board's current practices for administrative hearings to appeal CMPs. Specifically, we propose changes that would remove requirements to file submissions in triplicate and instead require electronic filing. This change is reflected in the proposed amendments to the definition of ''Filing date'' in § 156.901, to the introductory text in § 156.927(a), and to the service of submission requirements captured in paragraph (b). We also propose to allow for the option of video conferencing as a form of administrative hearing by amending the definition of ''Hearing'' in § 156.901 and to the requirements outlined in § 156.919(a) related to the forms for the hearing, § 156.941(e) related to prehearing conferences, and § 156.947(a) related to the record of the hearing. Finally, we propose to update § 156.947 to allow the ALJ to communicate the next steps for a hearing in either the acknowledgement of a request for hearing or on a later date. We seek comment on these proposals.

11. Quality Rating System (§ 156.1120) and Enrollee Satisfaction Survey System (§ 156.1125)

Section 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 quality and price. Section 1311(c)(4) of the PPACA directs the Secretary to establish an enrollee satisfaction survey that will assess enrollee satisfaction with each QHP offered through the Exchanges with more than 500 enrollees in the prior year.

Based on this authority, HHS finalized rules in May 2014 to establish standards and requirements related to QHP issuer data collection and public reporting of quality rating information in every Exchange.[207] 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 establishing quality standards for Exchanges and QHP issuers, collecting and reporting quality measure data, and displaying quality rating information across the Exchanges. Since 2015, we have collected clinical quality measure data and enrollee experience survey measure data and generated quality ratings to provide reliable, meaningful information about QHP quality performance data across Exchanges. In addition, since 2016, select states[208] with FFEs and State Exchanges have displayed QHP quality rating information as a tool for consumer decision-making while shopping for health insurance coverage in an Exchange. Beginning with the open enrollment period for plan year 2020, CMS displayed the QHP quality rating information for all Exchanges that used the *HealthCare.gov* platform, including the FFEs and SBE–FPs. State Exchanges that operated their own eligibility and enrollment platform were similarly required to display QHP quality ratings beginning with the open enrollment period for plan year 2020, but had some flexibility to customize the display of the QHP quality rating information.[209]

Through valuable feedback from the QRS and QHP Enrollee Survey Call Letter process and continued engagement with health plan issuer organizations, healthcare quality measurement experts, state representatives, consumer advocates and other stakeholders, we continue to learn about populations buying insurance coverage across the Exchanges and about areas of improvement for these programs. We also continue to assess potential refinements to the QRS rating methodology and the QHP Enrollee Survey to prioritize strategies to improve value for consumers and to reduce the burden of quality reporting.

As part of the 2020 QRS and QHP Enrollee Survey Call Letter process, we received many comments requesting that we remove levels of the QRS hierarchy to help streamline and improve consumer understanding of the quality rating information. While we are not proposing amendments to the QRS or to the QHP Enrollee Survey as part of this rulemaking, we seek comment on the removal of one or more levels of the QRS hierarchy, which is a key element of the QRS framework that establishes how quality measures are organized for scoring, rating and reporting purposes. We previously described the general overall framework for the QRS, including details on the hierarchical structure of the measure set and the elements of the QRS rating methodology.[210] Currently, the QRS measures are organized into composites, domains, and summary indicators that serve as a foundation for the rating methodology and scores are calculated at every level of the hierarchy using specific scoring and standardization rules, as described in the annual QRS and QHP Enrollee Survey Technical Guidance.[211] We believe that a simplified QRS hierarchy will support alignment with other CMS quality reporting programs and help the overall quality score be more reflective of the performance of individual survey and clinical quality measures within the QRS. For example, the Medicare Star Ratings framework consists of measures, domains, summary ratings and an overall rating.[212] In addition, we believe a simplified hierarchy, in combination with additional methodology modifications we are considering (for example, explicit weights at the measure level) will help stabilize ratings across years.[213] We seek comment specifically on which level or levels of the QRS hierarchy should be removed (for example, the composite level or the domain level).

In addition, to further support transparency of QHP quality data and to empower stakeholders including consumers, states, issuers and researchers with valuable information

[207] See 79 FR 30240 at 30352. Also see 45 CFR 155.1400, 155.1405, 156.1120 and 156.1125.

[208] Prior to the PY2020 nationwide display of quality rating information, states that displayed QHP quality rating information included California, Colorado, Connecticut, Maryland, Michigan, Montana, New Hampshire, New York, Rhode Island, Virginia, Washington, and Wisconsin.

[209] ''CMS Bulletin on display of Quality Rating System (QRS) star ratings and Qualified Health Plan (QHP) Enrollee Survey results for QHPs offered through Exchanges (often called the Health Insurance Marketplace),'' August 15, 2019. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QualityRatingInformationBulletinforPlanYear2020.pdf.*

[210] See, for example, 78 FR 69418.

[211] ''The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2021,'' September 2020. Available at *https://www.cms.gov/files/document/quality-rating-system-and-qualified-health-plan-enrollee-experience-survey-technical-guidance-2021.pdf.*

[212] ''Medicare 2019 Part C & D Star Rating Technical Notes,'' October 10, 2019. Available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Star-Ratings-Technical-Notes-Oct-10-2019.pdf.*

[213] CMS anticipates continuing to propose methodology refinements to the QRS and QHP Enrollee Survey through the Call Letter process.

related to enrollee experience with QHPs, we propose to make the full QHP Enrollee Survey results publicly available in an annual Public Use File (PUF). Currently, we post on *HealthCare.gov* some enrollee experience results in the form of a quality rating for Member Experience and Plan Administration that make up part of the overall rating for QHPs.[214] The Member Experience rating is based on a select number of survey measures from the QHP Enrollee Survey. The Plan Administration rating is based on a select number of survey measures and clinical quality measures. To promote transparency of data to the public, we already post QRS PUFs every year for QHP issuers operating in all Exchange types that were eligible to receive quality ratings. As we stated in the Exchange and Insurance Market Standards for 2015 and Beyond Final Rule, we have been considering different ways to make QHP quality data, including QHP Enrollee Survey results, publicly available and accessible to researchers, consumer groups, states and other entities.[215] Similar to the QRS PUFs, we propose to post a QHP Enrollee Survey PUF annually, beginning with the 2021 QHP Enrollee Survey results and during the 2022 open enrollment period, that would include the score and proportion of responses (for example, the percentage of respondents answering ''Never'' or ''Sometimes'') for every survey question and composite as well as demographic information such as employment status, race and ethnicity, and age at the reporting unit and national level to facilitate data transparency.

We solicit comment on this proposal.

12. Dispute of HHS Payment and Collections Reports (§ 156.1210)

In the 2014 Payment Notice, we established provisions related to the confirmation and dispute of payment and collection reports. These policies were finalized under the assumption that all issuers that receive APTCs would generally be able to provide these confirmations or disputes automatically to HHS. However, HHS has found that many issuers prefer to research payment errors and use enrollment reconciliation and disputes to update their enrollment and payment data, and may be unable to complete this research and provide confirmation or dispute of their payment and collection reports within 15 days, the timeline established by the 2014 Payment Notice.

In the 2021 Payment Notice, we amended § 156.1210(a) to lengthen the time to report payment inaccuracies from 15 days to 90 days to allow all issuers who receive APTCs 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. Additionally, at § 156.1210, we removed the requirement at paragraph (a) that issuers actively confirm payment accuracy to HHS each month, as well as the language in paragraph (b) regarding late filed inaccuracies. Instead, we amended paragraph (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.

Since finalizing these changes, HHS's experience has shown that some data inaccuracies reasonably will be identified after the 90-day reporting window. For example, issuers might receive notification of an Exchange Eligibility Appeals adjudication after the 90-day submission window. Additionally, some issuers are directed to update their enrollment and payment data after an HHS data review or audit which may occur after this 90-day window. In such instances it is in the interest of HHS, issuers, and enrollees to accept the late reporting of data inaccuracies. As such, we propose to amend § 156.1210 by redesignating current § 156.1210(b) to § 156.1210(d) and adding new § 156.1210(b) to establish a process for issuers to report enrollment or payment data changes in these situations.

We clarify that this proposed flexibility does not reduce an issuer's obligation to make a good faith effort to identify and promptly report discrepancies within the 90-day reporting window established under § 156.1210(a). Issuers can demonstrate good faith by sending regular and accurate enrollment reconciliation files and timely enrollment disputes throughout the applicable enrollment calendar year, 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. With respect to inaccuracies identified after the end of the applicable 90-day period, we propose to work with the issuer to resolve the inaccuracy if the issuer promptly notifies HHS, in a form and manner specified by HHS, no later than 15 days after identifying the inaccuracy. The failure to identify the inaccuracy in a timely manner in these situations must not have been due to the issuer's misconduct or negligence. For example, issuers must regularly submit quality monthly enrollment reconciliation files as required under § 156.265(f), and should regularly review monthly enrollment reconciliation files so that disputes are submitted in the 90-day reporting window. Disputes submitted after the expiration of the reporting window as a result of an issuer's failure to conduct these activities in a timely manner would not satisfy the good faith standard. We propose to codify these criteria at new proposed § 156.1210(b)(1) and (2).

Additionally, we propose to add paragraph (c) to allow the reporting of data inaccuracies after the 90-day period up to 3 years following the end of the plan year to which the inaccuracy relates or the date of the completion of the HHS audit process for such plan year, whichever is later. We believe this deadline will provide issuers with enough time to report any data inaccuracies discovered after the 90-day submission window, while providing a reasonable end date by which HHS, issuer and other stakeholders can consider the records for a particular benefit year closed.

We note that, pursuant to section 1313(a)(6) of the PPACA, ''[p]ayments made by, through, or in connection with an Exchange are subject to the False Claims Act (31 U.S.C. 3729 *et seq.*) if those payments include any Federal funds.'' As such if an issuer has an obligation to pay back APTCs, the issuer could be liable under the False Claims Act for knowingly and improperly avoiding the obligation to pay. We propose to codify in § 156.1210(c)(3), that, if a payment error is discovered after the 3-year or end of audit reporting deadline, the issuer is obligated to notify HHS and repay any overpayment. However, HHS will not pay the issuer after the 3-year or end of audit reporting deadline for any underpayments discovered.

We further clarify that the requirements of § 156.1210 apply to all issuers who receive APTCs, including issuers in State Exchanges. We seek comment on all aspects of this proposal, including its impact on the State

[214] A rating for Medical Care is the other component of the overall rating.

[215] 79 FR at 30311.

Exchanges' ability to resolve disputes and report payment adjustments to HHS in this timeframe.

We solicit comment on these proposals.

13. Payment and Collection Processes (§ 156.1215)

In the 2015 Payment Notice, HHS established a monthly payment and collections cycle for insurance affordability programs, user fees, and premium stabilization programs. As discussed above, we propose to eliminate state user fee collection flexibility that HHS had previously offered to states in 2017 Payment Notice, and propose to conforming amendments to remove the reference to ''State'' governments from paragraph (b). We seek comment on this proposal.

14. Administrative Appeals (§ 156.1220)

As detailed earlier in this preamble, we previously established a three-level administrative appeals process for issuers to seek reconsideration of amounts under certain PPACA programs, including the calculation of risk adjustment charges, payments and user fees. This process also applies to issuer disputes of the findings of a second validation audit (if applicable) as a result of HHS–RADV for the 2016 benefit year and beyond.[216] As explained in the 2020 Payment Notice, only those issuers who have insufficient pairwise agreement between the initial validation audit and second validation audit will receive a Second Validation Audit Findings Report and therefore have the right to appeal the second validation audit findings. In this rule, we propose to amend § 156.1220(a)(1)(vii) to add ''if applicable'' when discussing an issuer's ability to appeal the findings of the second validation audit to more clearly capture this limitation as part of the regulation, consistent with the existing language at § 153.630(d)(2) and the previously finalized policy. We propose a similar amendment in this rule to § 153.630(d)(3).

We also propose amendments to § 156.1220(a)(3) to clarify that the 30-calendar day timeframe to file a request for reconsideration of second validation audit findings (if applicable) or the risk score error rate calculation would be 30 calendar days from the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers. To capture this clarification, we propose to create a new proposed § 156.1220(a)(3)(ii) to specify the timeframe for filing a request for reconsideration for a risk adjustment payment or charge, including an assessment of risk adjustment user fees. This new proposed regulatory provision maintains the language that establishes a 30 calendar day window for these appeals that begin on the date of notification under § 153.310(e). We also propose to create a new proposed § 156.1220(a)(3)(iii) to separately address the timeframe for filing a request for reconsideration of second validation audit findings or the risk score error rate calculation and to add the phrase ''if applicable'' to more clearly capture the limitation on the ability to appeal second validation audit findings. To accommodate these two new proposed paragraphs, we also propose to amend § 156.1220 to redesignate paragraphs (a)(3)(iii) through (vi) as (a)(3)(iv) through (vii), respectively. We seek comment on these proposals.

15. Enrollment Process for Qualified Individuals (§ 156.1240)

Under § 156.1240(a), QHP issuers are required to accept a variety of payment methods so that individuals without a bank account or a credit card will have readily available options for making monthly premium payments. Specifically, paragraph (a)(1) requires QHP issuers to follow the premium payment process established by an Exchange in accordance with § 155.240. Paragraph (a)(2) requires QHP issuers to accept for all payments in the individual market, at a minimum, paper checks, cashier's checks, money orders, EFT, and all general-purpose pre-paid debit cards as methods of payment and present all payment method options equally for a consumer to select their preferred payment method. We propose to add new paragraph (a)(3) to require individual market QHP issuers to also accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA.

We have received questions indicating that there is some confusion over whether issuers must accept payments on behalf of an enrollee from an individual coverage HRA or QSEHRA. Individual coverage HRAs are a new type of health reimbursement arrangement that employers may offer to employees as of January 1, 2020. [217] In general, employers may offer individual coverage HRAs to their employees as a means of providing tax-advantaged reimbursements for medical care expenses, including premiums for individual health insurance coverage that they purchase for themselves and their families. QSEHRAs are another new type of HRA, established by the 21st Century Cures Act, enacted December 13, 2016, that qualified small employers can provide to their employees.[218] As explained in the final rule that adopted implementing regulations for individual coverage HRAs, certain aspects of which apply to QSEHRAs (final HRA rule),[219] reimbursement may include employee-initiated payments made through use of financial instruments, such as pre-paid debit cards, as well as direct payments, individual or aggregate, by the employer, employee organization, or other plan sponsor to the health insurance issuer.[220]

Consistent with the final HRA rule, we propose to add a new § 156.1240(a)(3) to require issuers offering individual market QHPs to accept payments of premiums that are received directly from an individual coverage HRA or QSEHRA that are made on behalf of an enrollee who is covered by the individual coverage HRA or QSEHRA. We propose that QHP issuers would be required to accept such payment when they are made using a method of payment described in § 156.1240(a)(2). We recognize some individual coverage HRAs and QSEHRAs prefer to make aggregate payments on behalf of multiple employees to a QHP issuer. We encourage QHP issuers to work with employers and administrators of individual coverage HRAs and QSEHRAs to facilitate this method of payment, as we believe this approach can ease administration of individual coverage HRAs and QSEHRAs. However, we are not proposing to require QHP issuers to accept payments from individual coverage HRAs or QSEHRAs when made using a form of payment that is not described in § 156.1240(a)(2). This proposal would help ensure that individual coverage HRAs or QSEHRAs operate as intended, and would address potential stakeholder confusion regarding whether QHP issuers must accept payments made from individual coverage HRAs or QSEHRAs.

[216] See 45 CFR 156.1220(a)(1)(vii).

[217] See 84 FR 28888.

[218] Public Law 114–255 (Dec. 13, 2016).

[219] 84 FR 28888 (June 20, 2019).

[220] See 84 FR at 28950–51 (''[E]mployer funds paid from an HRA go directly to a participant or a health insurance issuer because the economic substance of the transaction is the same—that is, the funds are being used to discharge an employee's premium payment obligations.'')

F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Definitions (§ 158.103)

To ensure program integrity, we propose to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that are deducted from incurred claims for MLR reporting and rebate calculation purposes.

Section 2718(a) of the PHS Act requires health insurance issuers to, for MLR purposes, separately report the percentage of premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under such coverage, on activities that improve health care quality, and on non-claims (administrative) costs. Section 158.140 sets forth the MLR reporting requirements related to the reimbursement for clinical services provided to enrollees, including a requirement that issuers must deduct from incurred claims prescription drug rebates received by the issuer.

In the May 14, 2020 **Federal Register** (85 FR 29164), we finalized amendments to the MLR rules at § 158.140(b)(1)(i) to require issuers to deduct from MLR 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 a PBM or other entity providing pharmacy benefit management services to the issuer. The applicability date for that amendment is the 2022 MLR reporting year (MLR reports filed in 2023).

During the regulatory process, we received numerous comments requesting HHS to codify and align the definition of prescription drug rebates and other price concessions that are reported by issuers for MLR purposes with the definition in section 1150A of the Act, as added by the PPACA,[221] which requires QHP issuers and PBMs to report certain prescription drug benefit information to HHS. The reference to rebates, discounts, and price concessions in section 1150A(b)(2) of the Act excludes bona fide service fees paid to PBMs by drug manufacturers or issuers. Under section 1150A of the Act, bona fide service fees are fees negotiated by PBMs that include but are not limited to ''distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs).'' Section 156.295, implementing section 1150A of the Act, defines bona fide services fees as ''fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.''

In light of these comments and the delayed applicability date of the amendment to § 158.140(b)(1)(i), we did not finalize a definition of ''prescription drug rebates'' or ''price concession'' in that rulemaking. Rather, we indicated that we would 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.

We propose to amend § 158.103 to add a definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes pursuant to § 158.140(b)(1)(i). We believe that codifying and clarifying the definition of prescription drug rebates and other price concessions will allow issuers to more accurately report the costs associated with enrollees' prescription drug utilization for purposes of the MLR calculation. This approach would also promote consistency in reporting across issuers. Therefore, we propose to amend the MLR rules to add the definition for prescription drug rebates and other price concessions to § 158.103 and to clarify that this term excludes bona fide service fees, consistent with how such fees are described in § 156.295. We propose that this provision become applicable beginning with the 2022 MLR reporting year (MLR reports filed in 2023), which aligns with the applicability date of the amendment to § 158.140(b)(1)(i) and should provide issuers with adequate time to adjust contracts with entities providing pharmacy benefit management services to provide transparency regarding prescription drug rebates and other price concessions they receive from drug manufacturers.

We seek comment on this proposal.

2. Premium Revenue (§ 158.130)

Section 2718(a) of the PHS Act requires health insurance issuers to submit an annual report to the Secretary that details the percentage of premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under health insurance coverage and on activities that improve healthcare quality. Section 158.130 specifies the reporting requirements with regard to earned premium, which must include all monies paid by a policyholder or subscriber as a condition of receiving coverage from the issuer, with certain adjustments.

In the August 4, 2020 guidance, Temporary Policy on 2020 Premium Credits Associated with the COVID–19 PHE, CMS adopted a temporary policy of relaxed enforcement to allow issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage to support continuity of coverage for individuals, families and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID–19 PHE.[222] On September 2, 2020, HHS issued an interim final rule on COVID–19 wherein we set forth MLR data reporting and rebate requirements for issuers offering temporary premium credits for 2020 coverage.[223] For the 2021 MLR reporting year [224] and beyond, we propose to adopt these MLR data reporting and rebate requirements for all health insurance issuers in the individual and small group markets [225] who elect to offer temporary premium credits during a PHE declared by the Secretary of HHS (declared PHE) in situations in which HHS issues guidance announcing its adoption of a

[221] The requirements of section 1150A with respect to QHP issuers are codified at § 156.295. In this proposed rule, we propose to amend that regulation and to codify the requirements with respect to PBMs at a new 45 CFR part 184.

[222] ''Temporary Policy on 2020 Premium Credits Associated with the COVID–19 Public Health Emergency,'' August 4, 2020. Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf.*

[223] 85 FR 54820 (Sept. 2, 2020).

[224] The MLR reporting year means a calendar year during which group or individual health insurance coverage is provided by an issuer. See 45 CFR 158.103. The 2021 MLR reporting year refers to the MLR reports that issuers must submit for the 2021 benefit year by July 31, 2022. See 45 CFR 158.110(b).

[225] While this proposed rule, the interim final rule on COVID–19 and the August 4, 2020 guidance focus on the individual and small group markets, to remove the barriers in support of issuers offering these premium credits to enrollees impacted by a PHE declared by the Secretary of HHS, we note that issuers in the large group market may also, when consistent with state law, offer temporary premium credits and should similarly report the lower, adjusted amount that accounts for the premium credits for MLR purposes.

similar temporary policy of relaxed enforcement to allow such issuers to offer temporary premium credits during the declared PHE.[226]

We propose that for purposes of § 158.130, issuers must account for temporary premium credits provided to enrollees during a declared PHE as reductions in earned premium for the applicable MLR reporting years, consistent with any technical guidance set forth in the applicable year's MLR Annual Reporting Form Instructions,[227] when such credits are permitted by HHS. Specifically, as clarified in the interim final rule on COVID–19, we propose that the amount of temporary premium credits [228] would constitute neither collected premium nor due and unpaid premium described in the MLR Annual Reporting Form Instructions for purposes of reporting written premium (which is a component of earned premium). Consequently, under this proposal, issuers who offer temporary premium credits during a declared PHE would report as earned premium for MLR and rebate calculation purposes the actual, reduced premium paid when such credits are permitted by HHS.

We request comment on this proposal.

3. Rebating Premium if the Applicable Medical Loss Ratio Standard Is Not Met (§ 158.240)

Section 2718(b) of the PHS Act, and the implementing regulations at §§ 158.210 and 158.240, require an issuer to provide an annual rebate to enrollees, on a pro rata basis, if the ratio of the amount of premium revenue expended by the issuer on reimbursement for clinical services provided to enrollees under the health insurance coverage and for activities that improve health care quality to the total amount of premium revenue (excluding federal and state taxes and licensing or regulatory fees) is less than 80 percent in the individual and small group markets and 85 percent in the large group market. In order to determine whether its MLR met the applicable standard, § 158.110(b) requires an issuer to submit to CMS, by July 31 of the year following the end of the MLR reporting year, an MLR Annual Reporting Form concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued.

Section 158.241 permits an issuer to provide MLR rebates in the form of a premium credit, lump-sum check, or, if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium. Issuers that choose to provide a rebate via a lump-sum check or lump-sum reimbursement to the account used to pay the premium must issue the rebate *no later than* September 30 following the end of the MLR reporting year pursuant to § 158.240(e). Issuers that elect to provide rebates in the form of a premium credit must apply the rebate to the first month's premium that is due *on or after* September 30 following the MLR reporting year pursuant to § 158.241(a)(2). This section also requires that when the rebate is provided in the form of a premium credit and the total amount of the rebate owed exceeds the premium due for October, any excess rebate amount must be applied to succeeding premium payments until the full amount of the rebate has been credited. Pursuant to § 158.240(f), an issuer that fails to pay a rebate owed to an enrollee in accordance with the applicable timeframes established in §§ 158.240(e) and 158.241(a)(2) is required to pay the enrollee the required rebate plus interest, at ten percent annually, accruing from the date payment was due.

On June 12, 2020, we announced a temporary policy of relaxed enforcement to allow issuers to prepay to enrollees a portion or all of the estimated MLR rebate for the 2019 MLR reporting year in the form of a premium credit, to the extent consistent with state law or other applicable state authority, in order to support continuity of coverage for enrollees who may struggle to pay premiums because of illness or loss of income resulting from the COVID–19 PHE.[229] This temporary policy of relaxed enforcement was limited to issuers that choose to prepay a portion or all of their estimated 2019 MLR rebate in the form of a premium credit, as the current rules do not prohibit issuers paying rebates in the form of a lump-sum check or lump-sum reimbursement to the account used to pay the premium from prepaying a portion or all of their rebates as long as the full rebate amount owed to an enrollee is paid to that enrollee *no later than* September 30 following the end of the MLR reporting year.[230]

Given the benefits experienced by enrollees in light of this temporary policy of relaxed enforcement during the COVID–19 PHE and our desire to continue to provide this flexibility for future years, we propose to amend § 158.240 by adding paragraph (g), which would explicitly allow issuers to prepay a portion or all of their estimated rebates to enrollees for any MLR reporting year regardless of the form in which they are paid. We believe that enrollees would generally benefit from the ability to receive estimated rebates earlier than contemplated by the timelines currently codified in §§ 158.240(e) and 158.241(a)(2) and prior to issuers submitting their MLR Annual Reporting Forms pursuant to § 158.110(b). We also propose to require that issuers that choose to prepay a portion or all of their estimated rebates do so for all eligible enrollees in a given state and market in a non-discriminatory manner.

In addition, under the current rules, an issuer that prepays a portion or all of its estimated rebate in the form of a lump-sum check, or if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium, and subsequently determines that such prepayment is less than the total rebate owed to an enrollee would have to incur the costs of disbursing rebates twice: First to disburse the prepaid rebate amount, and again to disburse the remaining rebate amount by the deadlines set forth in §§ 158.240(e) and 158.241(a)(2). To reduce the regulatory burden on issuers and incentivize issuers to deliver rebates to enrollees sooner, we propose to add to the proposed new § 158.240(g) a safe harbor under which an issuer that prepays at least 95 percent of the total rebate owed to enrollees in a given state and market for a given MLR reporting year by the MLR rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) may, without penalty or late payment interest under § 158.240(f), defer the payment of any remaining rebate owed to enrollees in that state and market until the MLR rebate payment deadlines set forth in

[226] The Secretary of HHS may, under section 319 of the PHS Act, determine that: (a) A disease or disorder presents a public health emergency; or (b) that a public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

[227] Available at *https://www.cms.gov/cciio/Resources/Forms-Reports-and-OtherResources/index#Medical_Loss_Ratio.*

[228] MLR rebates provided in the form of premium credits are different than the temporary premium credits such as those outlined in the August 4, 2020 guidance issued by CMS. When MLR rebates are provided in the form of premium credits, issuers must continue to report the full amount of earned premium and may not reduce it by the amount of MLR rebates provided in form of premium credits, as required by § 158.130(b)(3).

[229] ''Temporary Period of Relaxed Enforcement for Submitting the 2019 MLR Annual Reporting Form and Issuing MLR Rebates in Response to the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.'' (June 12, 2020). Available at *https://www.cms.gov/files/document/Issuing-2019-MLR-Rebates-in-Response-to-COVID-19.pdf.*

[230] 45 CFR 158.240(e).

§§ 158.240(e) and 158.241(a)(2) for the following MLR reporting year. This would enable such an issuer to maintain a single rebate disbursement cycle per year. Furthermore, the issuer would be able to combine payment of rebates remaining after prepayment with the rebates for the following MLR reporting year for enrollees who are enrolled with the issuer during both years. Enrollees who are no longer enrolled with the issuer the following year would receive only the rebates remaining after prepayment, but the issuer would still benefit by disbursing these amounts as part of the issuer's regular rebate disbursement process in the following year. At the same time, the proposed safe harbor would ensure that enrollees continue to receive most of the rebate within the regular timeframe, as issuers that prepay less than 95 percent of the total rebate owed to enrollees for a given MLR reporting year would continue to be required to provide the enrollees with the remaining portion of the rebate owed in accordance with the timeframes set forth in §§ 158.240(e) and 158.241(a)(2) for the current MLR reporting year. To further ensure that enrollees do not regularly receive reduced rebates as a result of prepayments, we also propose that under this safe harbor, the rebate amount remaining after prepayment would not be treated as *de minimis,* regardless of how small the remaining amount is. That is, the *de minimis* provisions in § 158.243 continue to apply only if the total rebate (the sum of the prepaid amount and any amount remaining after prepayment) owed to an enrollee for a given MLR reporting year is below the applicable threshold.

We note that § 158.250 requires issuers to provide a notice of rebates at the time any rebate is provided, which includes both rebate prepayments and payments of rebates remaining after prepayment. We intend to modify the ICRs approved under OMB Control Number 0938–1164 to add modified standard notices that can be used by issuers that elect to prepay rebates under the proposed new § 158.240(g). We also intend to revise the MLR Annual Reporting Form Instructions to clarify that an issuer that prepays a portion or all of its estimated rebate and subsequently determines that the amount of such prepayment is more than the total rebate owed to an enrollee for that MLR reporting year and that does not recoup the overpayment from the enrollee, may include the overpayment in its rebate payments reported for purposes of calculating the optional limit on the payable rebates under § 158.240(d). We additionally intend to revise the MLR Annual Reporting Form Instructions to clarify how issuers that prepay estimated rebates must report such prepayments.

We propose that this amendment to create new § 158.240(g) would be applicable beginning with the 2020 MLR reporting year (MLR reports filed in 2021). We seek comment on this proposal, including the proposed applicability date.

4. Form of Rebate (§ 158.241)

As discussed in the prior section of this preamble, § 158.241 permits an issuer to provide MLR rebates in the form of a premium credit, lump-sum check, or, if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium. Under § 158.240(e), issuers that choose to provide a rebate via a lump-sum check or lump-sum reimbursement to the account used to pay the premium must issue the rebate *no later than* September 30 following the end of the MLR reporting year. In contrast, § 158.241(a)(2) provides that issuers that elect to provide rebates in the form of a premium credit must apply the rebate to the first month's premium that is due *on or after* September 30 following the MLR reporting year, and that when the rebate is provided in the form of a premium credit and the total amount of the rebate owed exceeds the premium due in October, any excess rebate amount must be applied to succeeding premium payments until the full amount of the rebate has been credited.

Given the proposed addition of § 158.240(g) discussed in the prior section, the fact that an issuer may wish to provide rebates in the form of a premium credit earlier than October, and the desire to reduce the regulatory burden and enable enrollees to receive the benefit of rebates sooner, we propose to amend § 158.241(a)(2) to allow issuers to provide rebates in the form of a premium credit prior to the date that the rules currently provide. Specifically, we propose to amend § 158.241(a)(2) to specify that when provided in the form of premium credits, rebates must be applied to premium that is due no later than October 30 following the MLR reporting year. We propose that this amendment would be applicable beginning with the 2020 MLR reporting year (MLR reports due in 2021).

We seek comment on this proposal, including on the proposed applicability date.

G. Part 184—Pharmacy Benefit Manager Standards Under the Affordable Care Act

1. Prescription Drug Distribution and Cost Reporting by Pharmacy Benefit Managers (§§ 184.10 and 184.50)

PBMs are third-party administrators that manage the prescription drug benefit for a contracted entity.[231] This administration typically involves processing claims, maintaining drug formularies, contracting with pharmacies for reimbursement for drugs dispensed, and negotiating prices with drug manufacturers.[232]

The role of PBMs in the prescription drug landscape, including any impact on the rising cost of prescription drugs, is not well understood.[233] For example, PBMs generate revenue, in part, by retaining the difference between the amount paid by the health plan for prescription drugs and the amount the PBM reimburses pharmacies, a practice commonly referred to as ''spread pricing.'' While estimates report the increasing prevalence of spread pricing in private health insurance plans, [234] detailed data on the practice has generally not been collected by plans or by any state or federal regulatory body.

We propose to add part 184 to 45 CFR subchapter E to codify in regulation the statutory requirement that PBMs under contract with QHP issuers report the data described at section 1150A(b) of the Act to the Secretary and to each QHP for which the PBM administers the prescription drug benefit.

At proposed § 184.10(a)(1), we explain that new part 184 is based on section 1150A of the Act. At proposed § 184.10(b), we propose that the scope of new part 184 establishes standards for PBMs that administer prescription drug benefits for health insurance issuers which offer QHPs with respect to the offering of such plans. We also propose definitions for part 184 at new § 184.20. Except for the definition of pharmacy

[231] PBMs contract with a variety of health plans, including, but not limited to, individual and small group health plans, large group and self-insured plans, and Medicare Part D drug plans. In this section, we only reference PBMs that contract with a health insurance company to administer the prescription drug benefit for QHPs.

[232] ''Pharmacy Benefit Managers,'' Health Affairs Health Policy Brief, September 14, 2017. Available at *https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/.*

[233] Elizabeth Seeley and Aaron S. Kesselheim. ''Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead,'' Commonwealth Fund, March 2019. Available at *https://doi.org/10.26099/n60j-0886.*

[234] See ''The Prescription Drug Landscape, Explored.'' Available at *https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf.*

benefit manager, these proposed definitions would codify terms already in use in parts 144 and 155 of subchapter B of subtitle A of title 45 of the Code of Federal Regulations.

As part of the PPACA, Congress passed section 6005, which added section 1150A to the Act, requiring a PBM under a contract with a QHP offered through an Exchange established by a state under section 1311 of the PPACA [235] to provide certain prescription drug information to the QHP and to Secretary at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer and their PBM must report. Section 1150A(c) of the Act requires the Secretary to keep the information reported confidential and specifies that the information may not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.[236]

In the 2012 Exchange Final Rule, we codified the requirements of section 1150A of the Act, as it applies to QHPs, at § 156.295.[237] On January 1, 2020 [238] and on September 11, 2020 [239], we published **Federal Register** notices and solicited public comment on collection of information requirements detailing the proposed collection envisioned by section 1150A of the Act, as referenced earlier. As noted earlier in this preamble, we propose to revise § 156.295 to state that where a QHP issuer does not contract with a PBM to administer the prescription drug benefit for QHPs, the QHP issuer will report the data required by section 1150A of the Act to HHS.

We propose to add § 184.50(a) to state that where a PBM contracts with an issuer of QHPs to administer the prescription drug benefit for their QHPs, the PBM is required to report the data required by section 1150A(b) of the Act to the QHP and to the Secretary, at such times, and in such form and manner, as the Secretary shall specify. While we acknowledge that this section applies to both the QHP issuer and their PBMs to report this data, we propose to implement section 1150A to require PBMs to report this data directly to the Secretary, and only to require the QHP issuer to report the data only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs, as further discussed in the preamble to § 156.295 in this proposed rule.

We propose to add § 184.50(a)(1) through (3) to require these PBMs to report the data described at section 1150A(b) of the Act to the Secretary. The data proposed to be collected, as required by section 1150A, are: The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), that is paid by the health benefits plan or PBM under the contract; [240] the aggregate amount, and the type of rebates, discounts, or price concessions (excluding *bona fide* service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs [241]) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed; and the aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies (spread pricing), and mail order pharmacies, and the total number of prescriptions that were dispensed.

At new § 184.50(b) and (c), we also propose to codify the confidentiality and penalty provisions that appear at § 1150A(c) and (d) to PBMs which administer the prescription drug benefits for QHP issuers.

We seek comment on these proposals.

IV. Provisions of the Proposed Rule for State Innovation Waivers—Department of Health and Human Services and Department of the Treasury

A. 31 CFR Part 33 and 45 CFR Part 155—State Innovation Waivers

1. Section 1332 Application Procedures (31 CFR 33.108 and 45 CFR 155.1308), Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320), and Periodic Evaluation Requirements (31 CFR 33.128 and 45 CFR 155.1328)

Section 1332 of the PPACA permits states to apply for a State Innovation Waiver (also referred to as a section 1332 waiver or State Relief and Empowerment Waiver) to pursue innovative strategies for providing their residents with access to higher value, more affordable health coverage. The overarching goal of section 1332 waivers is to give all Americans the opportunity to obtain high value and affordable health coverage regardless of income, geography, age, sex, or health status, while simultaneously empowering states to develop health coverage strategies that best meet the needs of their residents. In this proposed rule, the Departments seek to provide states with consistency and predictability by codifying the Departments' long-standing policy published in the **Federal Register** in 2018, regarding how the Departments will apply section 1332 of the PPACA to determine whether applications for section 1332 waivers will be approved.

Under section 1332 of the PPACA, the Secretaries may exercise their discretion to approve a request for a section 1332 waiver only if the Secretaries determine that the proposal for the section 1332 waiver meets the following four requirements (referred to as the statutory guardrails): (1) The proposal will provide coverage that is at least as comprehensive as coverage defined in PPACA section 1302(b) and offered through Exchanges established by title I of PPACA, as certified by the Office of

[235] This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the PPACA. *King* v. *Burwell,* 576 U.S. 988 (2015).

[236] As noted earlier in this preamble, the purposes are: As the Secretary determines to be necessary to carry out Section 1150A or part D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the PPACA.

[237] Section 1150A(a)(1) also authorizes the collection of data from PBMs that manage prescription drug coverage under contract with a Prescription Drug Plan sponsor of a prescription drug plan or a Medicare Advantage organization offering a Medicare Advantage prescription drug plan.

[238] 85 FR 4993 through 4994.

[239] 85 FR 56227 through 56229.

[240] As stated above in the preamble for § 156.295, section 1150A(b)(1) requires the Secretary to collect data by pharmacy type. However, we are aware that it is not currently possible to report such data by pharmacy type because pharmacy type is a not standard classification currently captured in industry databases or files. To reduce burden, we are not proposing to collect data by pharmacy type at this time. We intend to collect this information at a time when the imposition of such a requirement would pose reasonable burden. We seek comment on ways that we may impose the collection of data by pharmacy type in the future without imposing unreasonable burden on the industry.

[241] This definition of bona fide service fees was finalized at § 156.295 in the 2012 Exchange Final Rule at 77 FR 18432. There, we finalized this definition to align with the definition of bona fide service fees finalized in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes final rule. See 77 FR 22072 at 22093.

the Actuary of CMS, based on sufficient data from the state and from comparable states about their experience with programs created by the PPACA and the provisions of the PPACA that would be waived; (2) the proposal will provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would be provided under title I of PPACA; (3) the proposal will provide coverage to at least a comparable number of the state's residents as would be provided under title I of PPACA; and (4) the proposal will not increase the federal deficit. The Secretaries retain their discretionary authority under section 1332 to deny waivers when appropriate given consideration of the application as a whole, even if an application meets the four statutory guardrails.

The Departments are also responsible under section 1332 of the PPACA for monitoring a waiver's compliance with the statutory guardrails and for conducting evaluations to determine the impact of the waiver. Specifically, section 1332 of the PPACA requires that the Secretaries provide for and conduct periodic evaluations of approved section 1332 waivers. The Secretaries must also provide for a process under which states with approved waivers must submit periodic reports concerning the implementation of the state's waiver program.

In October 2018, the Departments issued the 2018 Guidance,[242] which provides additional guidance for states that wish to submit section 1332 waiver proposals regarding the Secretaries' application review procedures, pass-through funding determinations, certain analytical requirements, and operational considerations. The 2018 Guidance also includes information regarding how the Departments will apply the section 1332 statutory guardrails to evaluate whether a waiver is approvable. Section 1332 of the PPACA and the 2018 Guidance empower states to address problems with their individual insurance markets and increase coverage options for their residents, and to encourage states to evaluate and adopt innovative strategies to reduce future overall health care spending. Together, the statutory guardrails and the 2018 Guidance provide states a reliable roadmap to follow in designing section 1332 waiver programs that will promote a stable health insurance market that offers more choice and affordability to state residents.

In this proposed rule, the Departments seek to provide certainty to states that the requirements and expectations of the section 1332 program will not change abruptly, or without notice to states and the public and an opportunity to comment, during a period in which states are doing the work to prepare a section 1332 waiver proposal that would satisfy the statutory guardrails or during a state's approved waiver period. Specifically, the Departments propose to incorporate the 2018 Guidance in full in the regulations governing section 1332 waiver application procedures, monitoring and compliance, and periodic evaluation requirements. The Departments are of the view that this proposal would give states greater certainty regarding how the Departments will apply section 1332's statutory guardrails when determining whether a state's waiver proposal can receive approval by the Departments and remain in compliance.

31 CFR 33.108 and 45 CFR 155.1308 specify the application procedures a section 1332 waiver proposal must meet to be approved by the Secretaries. Under these regulations, an application for initial approval of a section 1332 waiver will not be considered complete unless the application complies with the application procedures under 31 CFR 33.108(f) and 45 CFR 155.1308(f), including written evidence of the state's compliance with the public notice requirements set forth in 31 CFR 33.112 and 45 CFR 155.1312. Furthermore, an application must provide a comprehensive description of the enacted state legislation and program to implement a plan meeting the requirements for a waiver under section 1332; a copy of the enacted state legislation authorizing such waiver request; a list of the provisions of law that the state seeks to waive including a brief description of the reason for the specific request; and the analyses, actuarial certifications, data, assumptions, targets and other information sufficient to provide the Secretaries with the necessary data to determine that the state's proposed waiver meets the statutory guardrails. The 2018 Guidance provides supplementary information about the requirements that must be met for the approval of a State Innovation Waiver, the Secretaries' application review procedures, the calculation of pass-through funding, certain analytical requirements, and operational considerations. The 2018 Guidance also describes ways in which a section 1332 state plan may meet section 1332 requirements in order to be eligible to be approved by the Secretaries, clarifying the adjustments the Secretaries may make to maintain federal deficit neutrality, and allowing for states to use existing legislative authority to authorize section 1332 waivers in certain scenarios. The Departments are of the view that using consistent application requirements will encourage more states to pursue waivers without the worry that some of the rules may change after they have submitted a waiver application. Furthermore, by referencing and incorporating the full guidance into regulations, this proposal would allow states to plan for future waiver applications. The Departments are of the view that this proposal will provide certainty to states as they invest significant state resources towards submission of a section 1332 waiver and implementation of a section 1332 waiver, particularly waivers that require multiyear preparation.

This proposed rule proposes to incorporate the 2018 Guidance in full in the Departments' monitoring and compliance regulations at 31 CFR 155.1320 and 45 CFR 155.1320. Specifically, under the current requirements the Secretaries reserve the right to suspend or terminate a waiver, in whole or in part, any time before the date of expiration, if the Secretaries determine that the state materially failed to comply with the terms and conditions of the waiver. The Departments will review and, when appropriate, investigate documented complaints that the state is failing to materially comply with requirements specified in the approved waiver and the specific terms and conditions (STCs) for the approval of the waiver signed by the Departments and the state. In addition, the Departments will promptly share with the state any complaint that they may receive and will notify the state of any applicable monitoring and compliance issues. Additionally, states with approved section 1332 waivers must comply with all applicable federal laws and regulations (unless specifically waived) and must come into compliance with any changes in federal law or regulations affecting section 1332 waivers. The Departments are of the view that this proposal to incorporate the full 2018 Guidance in the monitoring and compliance requirements will provide certainty regarding how the Departments will evaluate and review section 1332 waiver programs, as states submit information concerning the implementation of the waiver program.

This proposed rule also proposes to incorporate the 2018 Guidance in full in the periodic evaluation requirements regulations at 31 CFR 33.128 and 45 CFR 155.1328. Under current

[242] 83 FR 53575 (Oct. 24, 2018).

requirements, the Departments are responsible for evaluating the waiver using federal data, information reported by states, and the waiver application itself to ensure that the Departments can exercise appropriate oversight of the approved waiver. Per 31 CFR 33.120(f) and 45 CFR 155.1320(f), the state must fully cooperate with the Departments or an independent evaluator selected by the Departments in consultation with the state, to undertake an independent evaluation of any component of the section 1332 waiver. As part of this required cooperation, the state must submit all requested data and information to the Departments or the independent evaluator. The state generally must meet the statutory requirements in each year that the waiver is in effect, as such the primary focus of the periodic evaluations will be the four statutory guardrails. However, the Departments will consider the longer-term impacts of a state's proposal. The Departments are of the view that this proposal to incorporate the full 2018 Guidance in the periodic evaluation requirements will provide certainty regarding how the Departments will evaluate whether a section 1332 waiver may maintain its approval by the Departments. The Departments also believe that this proposal will also help states to anticipate the data that will be most relevant and helpful to the Departments' analyses of a state's compliance with the specific terms and conditions approved by the Departments.

As such, the Departments specifically propose to revise the language in 31 CFR 33.108(f)(3)(iv), 31 CFR 33.120(a)(1), 31 CFR 33.128(a), 45 CFR 155.1308(f)(3)(iv), 45 CFR 155.1320(a)(1), and 45 CFR 155.1328(a) to incorporate the 2018 Guidance in full. The Departments are of the view that the increased certainty that would result from incorporating the full 2018 Guidance as proposed into the section 1332 implementing regulations will allow states to have greater confidence that the significant time and monetary investments necessary to plan for and submit a section 1332 waiver application will not result in wasted resources and taxpayer dollars. The Departments are also of the view that this proposed rule will help to increase state innovation, which could lead to more affordable health coverage for individuals and families in states that implement a section 1332 waiver program. The Departments seek comment on these proposals.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. This proposed 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 11. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following ICRs.

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.[243] Table 10 in this proposed 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 10—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES

Occupation title	Occupational code	Mean hourly wage ($/hr.)	Fringe benefits and overhead ($/hr.)	Adjusted hourly wage ($/hr.)
Compliance Officer	13–1041	$35.03	$35.03	$70.06
Pharmacy Technician	29–2052	16.95	16.95	33.90
Secretaries and Administrative Assistants	43–6014	18.84	18.84	37.68
Billing and Posting Clerks	43–3021	19.53	19.53	39.06
Chief Executives	11–1011	93.20	93.20	186.40
Business Operations Specialist	13–1198	38.57	38.57	77.14
Computer System Analyst	15–1121	46.23	46.23	92.46
Computer Programmer	15–1251	44.53	44.53	89.06
Computer and Information Systems Manager	11–3021	75.19	75.19	150.38
General and Operations Manager	11–1021	59.15	59.15	118.30
Auditor	13–2011	38.23	38.23	76.46

B. ICRs Regarding State Flexibility for Risk Adjustment (§ 153.320)

We are proposing to allow state regulators to request a reduction in the calculation of risk adjustment transfers under the state payment transfer formula under § 153.320(d) for up to 3 years, beginning for the 2023 benefit year. HHS would require any state that intends to request multi-year flexibility to submit its request by August 1st of the calendar year that is 2 calendar

[243] See May 2019 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at *https://www.bls.gov/oes/current/oes_stru.htm.*

years prior to the beginning of the first benefit year of its request. HHS would reserve the right to require states with approved multi-year reduction requests to submit supplemental evidence in any subsequent year of the request after its initial approval, in the timeframe, form, and manner specified by HHS, and would also reserve the right to terminate or modify an approved multi-year reduction request prior to its natural expiration. We propose to permit states with approved multi-year requests to withdraw their respective request before its natural expiration by notifying HHS of its requested withdrawal. We also propose to require states to inform impacted issuers of any early termination, modification, or withdrawal of a multi-year reduction request. We expect that fewer than 10 states would make these requests annually. Therefore, we believe that this collection is exempt from the PRA under 44 U.S.C. 3502(3)(A)(i).

C. ICRs Regarding Submission of Adjusted Premium Amounts for Risk Adjustment

45 CFR 153.610 and 153.710 provide that issuers of a risk adjustment covered plan must provide HHS with access to risk adjustment data through a dedicated distributed data environment (EDGE server), in a manner and timeframe specified by HHS. We clarify that, for purposes of risk adjustment data submissions in the 2021 benefit year and beyond when a declared PHE is in effect and HHS permits these premium credits, issuers that choose to provide premium credits must submit the adjusted (that is, lower) plan premiums for those months, instead of the unadjusted plan premiums. HHS would require issuers to submit adjusted plan premiums to their EDGE servers for all enrollees whom the issuer has actually provided premium credits as a reduction to the corresponding benefit year premiums. We do not believe that issuers who elect to provide these premium credits will incur additional operational burden associated with EDGE server data submissions as a result of these requirements because we expect issuers' premium reporting systems will already be configured to enable issuers to upload the billable premiums actually charged to enrollees for the applicable benefit year to the EDGE server. Additionally, the current EDGE server operational guidance for the risk adjustment program allows issuers to submit billable premium changes so there will be no changes to the data submission rules. The burden related to this information collection is currently approved under OMB control number 0938–1155 (Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals). The information collection request expires on February 23, 2021.

D. ICRs Regarding Direct Enrollment (§§ 155.220 and 155.221)

At § 155.220(c)(3)(iii), we are proposing to require web-brokers' non-Exchange websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), including a standardized disclaimer provided by the Exchange if the web-broker non-Exchange website does not facilitate enrollment in all QHPs offered through the Exchange, before assisters would be permitted to use the web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment. The Exchange would provide the exact text for this disclaimer and the language would not need to be customized.

At § 155.220(c)(6), we propose a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's non-Exchange website being used to complete an Exchange eligibility application or a QHP selection, which may include submission of a number of artifacts of documentation or completion of certain testing processes. The required documentation may include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. We estimate that it would take up to 2 hours for a Business Operations Specialist (at an hourly cost of $77.14) to complete and submit the required operational data and web-broker agreement to HHS each year. We estimate that it would take up to 17 hours for a Business Operations Specialist (at an hourly cost of $77.14) to complete and submit the required security and privacy assessment documentation to HHS. The total burden for each web-broker would be approximately 19 hours, with an equivalent cost of approximately $1,466. Based on current web-broker participation and potential market size, we estimate that 30 web-brokers would participate. We estimate that these data collections would have an annual burden of 570 hours with a cost of approximately $43,970.

We propose to add additional detail to the operational readiness requirement in § 155.221(b)(4) to incorporate requirements for direct enrollment entities seeking approval to use the EDE pathway. In proposed § 155.221(b)(4), we propose a direct enrollment entity must demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection, which may include submission of a number of artifacts of documentation or completion of various testing or training processes. The required documentation could include business audit documentation including: Notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation could also include security and privacy audit documentation including: Interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; vulnerability scan results; and an agreement between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program. We estimate that for each direct enrollment entity it would take up to 9 hours for a Business Operations Specialist (at an hourly cost of $77.14) to complete and submit a typical documentation package and related information to HHS each year. Based on current EDE participation and potential market size, we estimate that 77 EDE entities would participate in a manner such that they would be required to submit this type of information, and therefore, this data collection would have an annual burden of 693 hours with an annual cost of approximately $53,458. In addition, we estimate that it would take up to 72 hours for an Auditor (at an hourly cost of $76.46) to complete and submit a business requirements audit package for a direct enrollment entity, including audit report and testing results, to HHS. Based on current EDE participation and

potential market size, we estimate that four EDE entities would participate, and therefore this data collection would have an annual burden of 288 hours with a cost of approximately $22,020. We also estimate that it would take up to 122 hours for an Auditor (at an hourly cost of $76.46) to complete and submit a security and privacy audit package for a direct enrollment entity to HHS each year. Based on current EDE participation and potential market size, we estimate that 14 EDE entities would participate, and therefore this data collection would have an annual burden of 1,708 hours with a cost of approximately $130,594.

E. ICRs Regarding Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295) and PBMs (§ 184.50)

We propose to revise § 156.295 and add § 184.50 to require QHP issuers or PBMs that contract with QHP issuers to report the data envisioned by section 1150A. We have not previously collected this data; therefore, the burden associated with these proposals would reflect the imposition of the burden for a new collection, and not merely the burden created by changes to existing regulatory text. On January 1, 2020 [244] and on September 11, 2020,[245] we published notices in the **Federal Register** and solicited public comment on the burden related to these ICRs. Here, we replicate the discussion regarding burden from the information collection published in September 2020 and solicit a third round of public comment on the burden associated with this collection.

The burden associated with this collection is attributed to QHP issuers and PBMs, and the burden estimates were developed based on our previous experience with QHP information reporting activities. We are unaware of any QHP issuer that does not contract with a PBM to administer their prescription drug benefit. While we invite comment on whether any QHP issuer does not use a PBM, we do not currently estimate any burden for a QHP issuer to submit data directly. The following burden estimate reflects our expectation that all data would be submitted by PBMs.

Across all 50 states and the District of Columbia, we estimate approximately 40 PBMs would be subject to the reporting requirement. We further estimate that these PBMs, taken as a whole, annually contract with approximately 275 QHP issuers to administer the prescription drug benefit for their QHPs. We estimate that the 275 QHP issuers offer 7,000 total QHPs annually or 25.4 QHPs per QHP issuer. Thus, we estimate that each of the 40 PBMs would report data for 175 QHPs on average each year. We understand that some of these PBMs would contract with more QHP issuers than others, and as such, the reporting requirement would vary per PBM. We seek comment on the number of PBMs and the number of QHPs estimated.

Each PBM that administers pharmacy benefits for a QHP issuer would be required to complete a web form and a data collection instrument. The web form would collect data aggregated at the QHP issuer level for all plans and products offered by the QHP issuer combined. The web form would also require the reporting of an allocation methodology that is selected by the PBM to allocate data, where necessary. We would expect submitters to maintain internal documentation of the allocation methodologies chosen, as CMS may need to follow-up with the submitter to better understand the methodology.

PBMs would prepare and submit one data collection instrument per QHP issuer by Health Insurance Oversight System (HIOS) ID. Each data collection instrument would contain information regarding each plan the issuer offers. We estimate that an average PBM would report information for 5,200 NDCs for each QHP. The reports must include the data for all of the plans that the QHP issuer offered in their QHPs in the applicable plan year, even if they have no data to report for that plan year.

Each submitter would also be required to complete an attestation which confirms the data submitted is accurate, complete, and truthful.

We estimate that 40 PBMs would submit data for this reporting requirement, each submitting data for 175 QHPs on average. For each PBM, we estimate that it would take compliance officers approximately 570 hours (for an annual cost of approximately $39,934 at a rate of $70.06 per hour), pharmacy technician 350 hours (for an annual cost of $11,865 at a rate of $33.90 per hour), secretaries and administrative assistants 175 hours (for an annual cost of $6,594 at a rate of $37.68 per hour), and billing and posting clerks 175 hours (for an annual cost of approximately $6,836 at a rate of $39.06 per hour) to prepare and submit the information and 8 hours for a chief executive (for an annual cost of approximately $1,491.20 at a rate of $186.40 per hour) to review the information and complete the attestation. In total, we estimate it will take a PBM approximately 1,278 hours to respond to this reporting requirement each year on average, for a total annual cost of approximately $66,719 per PBM to report data. This estimate will vary by PBM, since each PBM will report for a different number of plans, depending on the number of QHPs offered by a particular QHP issuer. Thus, we estimate the total annual burden for all 40 PBMs combined to be approximately 51,120 hours or $2,668,796.

We estimate that PBMs would incur burden to complete a one-time technical build to implement the changes necessary for this collection, which would involve activities such as planning, assessment, budgeting, contracting, and reconfiguring systems to generate data extracts that conform to this collection's requirements. We assume that this one-time burden would be incurred primarily in 2021. We estimate that, for each PBM, on average, it would take project management specialists and project management specialists and business operations specialists 500 hours (at $77.51 per hour), computer system analysts 1,300 hours (at $92.46 per hour), computer programmers 2,080 hours (at $89.06 per hour), computer and information systems managers 40 hours (at $150.38 per hour) and general and operations managers 50 hours (at $118.30 per hour) to complete this task. The total one-time burden for a PBM would be approximately 3,970 hours on average, with an equivalent cost of approximately $356,128. For all 40 PBMs, the total one-time burden would be 158,800 hours for a total cost of approximately $14.2 million. For all 40 PBMs, the average annual burden in 2021–2023 incurred for implementation and reporting would be approximately 87,013 hours with an average annual cost of approximately $6.5 million.

We estimate that 275 QHP issuers would need to identify for the PBMs each year which plans are QHPs. For each QHP issuer, we estimate that it would take secretaries and administrative assistants 7 hours (for an annual burden of $263.76 at a rate of $37.68 per hour) to identify, on average, approximately 25 QHPs offered by a QHP issuer. This estimate will vary by QHP issuer, since each QHP issuer would identify a different number of QHPs, depending on the number of QHPs offered by a particular QHP issuer. Thus, we estimate the total annual burden for all 275 QHP issuers combined to be 1,925 hours or approximately $72,534.

F. ICRs Regarding Medical Loss Ratio (§§ 158.103, 158.130, 158.240, 158.241)

We propose to amend § 158.103 to establish the definition of prescription

[244] 85 FR 4993 through 4994.

[245] 85 FR 56227 through 56229.

drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes pursuant to § 158.140(b)(1)(i). We propose that issuers that elect to provide temporary premium credits to consumers during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond must account for these credits as reductions to premium for the applicable months when reporting earned premium for the applicable MLR reporting year. We also propose to add a new § 158.240(g) to explicitly allow issuers to prepay a portion or all of their estimated MLR rebates to enrollees for a given MLR reporting year, and to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. In addition, we propose to amend § 158.241(a)(2) to allow issuers to provide MLR rebates in the form of a premium credit prior to the date that the rules currently provide. Finally, we propose to clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits during a PHE declared by the Secretary of HHS in the 2021 benefit year and beyond when such credits are permitted by HHS. We anticipate that implementing these provisions would require minor changes to the MLR Annual Reporting Form, but would not significantly increase 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)). The control number is currently set to expire on October 31, 2020. A revised collection of information seeking OMB approval for an additional 3 years is currently under review by OMB.

G. ICRs Regarding State Innovation Waivers (31 CFR 33.108, 45 CFR 155.1308, 31 CFR 33.120, 45 CFR 155.1320, 31 CFR 33.128 and 45 CFR 155.1328

In this proposed rule, the Departments propose to reference and incorporate the existing 2018 Guidance in full into the section 1332 waiver implementing regulations in order to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments. This rule does not propose to alter any of the requirements related to state innovation waiver applications, compliance and monitoring, or evaluation in a way that would create any additional costs or burdens for states seeking waiver approval or those states with approved waiver plans. The Departments anticipate that implementing these provisions would not significantly change the associated burden. The burden related to this information collection (Review and Approval Process for Waivers for State Innovation (CMS–10383)) is currently under review by OMB.

H. ICRs Regarding Special Enrollment Period Verification (§ 155.420)

State Exchanges provide periodic reporting of Exchange enrollment data to CMS, including enrollments through SEPs by type, under OMB 0938–1119. We anticipate this PRA would cover the collection of this information. We will separately notice updates to this PRA package, if any, associated with this proposal.

I. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 11—PROPOSED 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 ($)	Total cost ($)
§ 155.220(c)(6)	0938–NEW	30	30	19	570	$43,970	$43,970
§ 155.221(b)(4)	0938–NEW	77	77	9	693	53,458	53,458
§ 155.221(b)(4)—Business Requirements Audit.	0938–NEW	4	4	72	288	22,020	22,020
§ 155.221(b)(4)—Security and Privacy Audit.	0938–NEW	14	14	122	1,708	130,594	130,594
156.295 & 184.50 (PBM Burden).	0938–NEW	40	40	2,175	87,013	6,527,571	6,527,571
156.295 & 184.50 (QHP Issuer Burden).	0938–NEW	275	275	7	1,925	72,534	72,534
Total		440	440		92,197	6,850,147	6,850,147

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 11.

J. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS's website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential ICRs. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–9914–P), the ICR's CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due February 2, 2021.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

This rule proposes standards related to the risk adjustment program for the 2022 benefit year and beyond. Additionally, this rule proposes the premium adjustment percentage and associated parameters and FFE and SBE–FP user fees for the 2022 benefit year. It also includes proposed changes related to special enrollment periods; Navigator program standards; direct enrollment entities; and the administrative appeals process with

respect to health insurance issuers and non-federal governmental group health plans; and the medical loss ratio program. It also proposes changes to the regulation to require the reporting of certain prescription drug information for QHPs or their PBM. In addition, it proposes to create a new direct enrollment option for State Exchanges and FFE states. In addition, relating to State Innovation Waivers, it proposes to reference and incorporate sections of the 2018 Guidance into the section 1332 waiver implementing regulations in order to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments.

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 one 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 one 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 one 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 one year, and therefore, meets the definition of ''significant rule'' 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 OMB.

The provisions in this proposed rule aim to ensure that consumers continue to have access to affordable coverage and health care, and that states have flexibility and control over their insurance markets. They would reduce regulatory burden, reduce administrative costs for issuers, web-brokers and direct enrollment entities, and states, ensure greater market stability, increase transparency and availability of QHP survey data, and increase transparency on the impact of PBMs on the cost of prescription drugs for QHPs. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these proposed provisions are expected to increase access to affordable health coverage.

Affected entities, such as Exchanges, issuers and FFE Classic Direct Enrollment and Enhanced Direct Enrollment partners, would incur costs to implement new special enrollment period requirements; State Exchanges would incur costs to implement and operationalize special enrollment period verification; and web-brokers and direct enrollment entities would incur costs to comply with operational readiness demonstration requirements. QHP issuers and PBMs would incur costs to implement and operationalize drug data reporting. 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 A–4, Table 12 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This proposed rule implements standards for programs that will have numerous effects, including allowing consumers to have continued access to coverage and health care, 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 proposed rule. The effects in Table 12 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this proposed rule for health insurance issuers and consumers. The annual monetized transfers described in Table 12 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers.

We are proposing the risk adjustment user fee of $0.25 PMPM for the 2022 benefit year to operate the risk adjustment program on behalf of states,[246] which we estimate to cost approximately $60 million in benefit year 2022. We expect risk adjustment user fee transfers from issuers to the federal government to remain steady at $60 million, the same as those estimated for the 2021 benefit year.

For 2022, we are considering two additional proposals. First, we are proposing to reduce the FFE user fee rate from 3.0 percent of total premiums charged to 2.25 percent of total premiums charged, and we propose to reduce the SBE–FP user fee rate from 2.5 percent of total premiums charged to 1.75 percent of total premiums charged. For the 2023 benefit year, we propose FFE–DE and SBE–FP–DE user fee rate of 1.5 percent of total premiums charged. While our current budget estimates may change in the future, we believe that it is important to keep the user fee in all markets at the lowest level possible to cover the costs of the Exchanges to keep premiums low for consumers and issuers. We expect transfers from the issuers to federal government to be reduced by approximately $270 million in 2022 and by approximately $400 million in 2023 due to changes in user fee rates and state transitions; transitions from FFE or SBE–FP to State Exchange, SBE–FP, or FFE–DE are included in the reduction in user fee

[246] As noted earlier in this proposed 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 from issuers to federal government.

TABLE 12—ACCOUNTING STATEMENT

Benefits:

Qualitative:
- Continued access to coverage and heath care due to new special enrollment periods.
- Greater market stability resulting from updates to the risk adjustment methodology.
- Strengthened program integrity related to the proposal to require Exchanges to conduct special enrollment period verification.
- Increased probability that consumers are able to maintain continuous coverage as a result of receiving MLR rebates sooner.
- Increased transparency on the impact of PBMs on the cost of prescription drugs for QHPs.
- Increased certainty for states regarding the application and ongoing approval process for section 1332 waiver applications, leading to increase in state innovation.

Costs	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	$7.02	2020	7	2021–2025
	6.88	2020	3	2021–2025

Quantitative:
- Costs incurred by web-brokers and direct enrollment entities to comply with requirements related to demonstration of operational readiness and compliance with applicable requirements; and by issuers and PBMs to implement and operationalize drug data reporting, as detailed in the Collection of Information Requirements section, estimated to be approximately $14.5 million in 2021 and approximately $3 million 2022 onwards.
- Reduction in potential costs for states submitting multi-year state flexibility requests estimated to be approximately $22,000 over 3 years, starting with request submissions in 2021.
- Costs incurred by issuers of risk adjustment covered plans for audits, audits of issuers of reinsurance eligible plans, and audits of APTC, CSR, and user fee programs, estimated to be approximately $2 million on average annually in 2021–2025.
- Costs incurred by State Exchanges to implement and operationalize special enrollment period verification, estimated to be one-time costs of approximately $108 million incurred over 2021–23 and ongoing annual costs of approximately $1.4 million in 2024 and 2025.
- Reduction in potential costs to Exchanges since they would 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 savings of $113 million in 2022.
- Regulatory familiarization costs of approximately $27,000 in 2020.

Qualitative:
- Increased costs due to increases in providing medical services (if health insurance enrollment increases).

Transfers	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	−$280.5	2020	7	2021–2025
	−287.8	2020	3	2021–2025

Quantitative:
- Reduction in transfers from the issuers to federal government by approximately $270 million in 2022 and approximately $400 million 2023 onwards due to changes in user fee rates and state transitions, including the proposed availability of FFE–DE and SBE–FP DE options to issuers and states beginning with the 2023 benefit year.
- Transfers to the federal government from FFE states that are transitioning to, or intend to transition to, being State Exchanges, for conducting special enrollment verification, estimated to be approximately $1.75 million annually in 2024 and 2025.

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 12 or 13. Table 13 summarizes the effects of the risk adjustment program on the federal budget from fiscal years 2022 through 2026, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of this proposed rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 13.

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. These analyses exclude any potential effects from states electing to use the FFE–DE or SBE–FP–DE models. Based on these internal analyses, we anticipate that the quantitative effects of the provisions proposed in this rule are consistent with our previous estimates in the 2021 Payment Notice for the impacts associated with the APTCs, the premium stabilization programs, and FFE user fee requirements.

TABLE 13—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT AND REINSURANCE PROGRAMS FROM FISCAL YEAR 2022–2026, IN BILLIONS OF DOLLARS [247]

Year	2022	2023	2024	2025	2026	2022–2026
Risk Adjustment and Reinsurance Program Payments	6	6	7	7	8	34

[247] Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.

TABLE 13—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT AND REINSURANCE PROGRAMS FROM FISCAL YEAR 2022–2026, IN BILLIONS OF DOLLARS [247]—Continued

Year	2022	2023	2024	2025	2026	2022–2026
Risk Adjustment and Reinsurance Program Collections	6	6	7	7	8	34

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.* March 6, 2020. Available at *https://www.cbo.gov/system/files/2020-03/51298-2020-03-healthinsurance.pdf.*

1. Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets (§ 147.104)

The proposed revision to § 147.104(b)(4)(ii) would allow an individual or dependent who did not receive timely notice of a triggering event and otherwise was reasonably unaware that a triggering event occurred to use the date the individual knew, or reasonably should have known, of the occurrence of the triggering event as the date of the triggering event for a special enrollment period to enroll in individual market coverage through or outside of an Exchange. This would enable consumers to maintain continued access to coverage and health care.

2. CMS Enforcement in Group and Individual Markets (Part 150)

We propose to remove the requirement to file submissions to the Departmental Appeals Board in triplicate and instead require electronic filing. Based on our experience, such filings are infrequent, and this proposed change would not have a significant impact. An entity filing a submission would experience a small reduction in costs related to printing and mailing the submission.

3. Risk Adjustment (Part 153)

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 2022 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 2022 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 2022 benefit year are expected to remain steady from the prior 2021 benefit year estimates of 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 2022 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 2022 benefit year, we expect the final risk adjustment user fee for the 2022 benefit year to neither increase or decrease transfers from issuers of risk adjustment covered plans to the federal government.

Additionally, for the risk adjustment factors, we proposed to recalibrate the HHS risk adjustment models for the 2022 benefit year by using the 2016, 2017 and 2018 enrollee-level EDGE data, the same data used for the 2021 benefit year. We adopted 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 2021 benefit year to the 2022 benefit year. We also propose, for the 2022 benefit year, to make model specification changes to the risk adjustment models to add a two-stage specification and interacted HCC counts factors to the adult and child risk adjustment models, to revise the enrollment duration factors for the adults models and to continue a pricing adjustment for Hepatitis C drugs for all three models (adult, child and infant). Overall, these proposed changes would make limited changes to the number and type of risk adjustment model factors; therefore, we do not expect these changes to impact issuer burden beyond the current burden for the risk adjustment program.

We propose that issuers that choose to offer premium credits to consumers during a declared PHE, when HHS permits such credits, must report the adjusted plan premium amount, taking into account the credits provided to consumers as a reduction to premiums for the applicable months for risk adjustment data submissions for the 2021 benefit year and beyond. We do not believe that the clarifications regarding risk adjustment reporting in this proposal would impose additional administrative burden on health insurance issuers beyond the effort already required to submit data to HHS for the purposes of operating risk adjustment, as previously estimated in the interim final rule on COVID–19 (85 FR 54820).

In the 2021 Payment Notice, HHS finalized the risk adjustment state payment transfer formula under the HHS risk adjustment methodology for the 2021 benefit year, and reaffirmed that HHS will continue to operate the risk adjustment program in a budget neutral manner. We propose to maintain the same methodology and continue to operate risk adjustment in a budget neutral manner for the 2022 benefit year and beyond, unless changed through notice with comment rulemaking. Therefore, there is no net aggregate financial impact on health insurance issuers or the federal government as a result of the risk adjustment provisions with respect to the premium credit related proposals. However, while risk adjustment transfers are net neutral in aggregate, we recognize that individual issuers may be financially impacted by reduced transfers (either lower risk adjustment payments or lower risk adjustment charges) if any issuer in the issuer's state market risk pool provides premium credits to enrollees. The extent of this impact will vary based on the number of issuers in a state market risk pool that elect to provide the temporary premium credits during a declared PHE, the amount of these premium credits provided, as well as the market share of

the issuers that provide these premium credits.

We do not believe that the impact of this proposal will vary from what was previously estimated in the interim final rule on COVID–19 (85 FR 54820). Similar to our analysis of regulatory impacts in the interim final rule on COVID–19, we recognize the potential for financial impacts for individual issuers as a result of the clarifications in this proposal. We believe that if HHS permitted issuers that provided premium credits to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur which could also financially impact individual issuers. For example, absent the requirement that issuers that offer premium credits report the adjusted, lower premium amount for risk adjustment purposes, an issuer with a large market share with higher-than-average risk enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same state market risk pool that owes a risk adjustment charge, and also provides premium credits to enrollees, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that reflected the actual, reduced premium charged to enrollees by issuers in the state market risk pool.

For all of these reasons, we believe that requiring issuers that offer temporary premium credits for 2021 and future benefit years' coverage to accurately report to the EDGE server the adjusted, lower premium amounts actually charged to enrollees is most consistent with existing risk adjustment program requirements. We also believe this requirement would mitigate the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts charged to enrollees, while avoiding additional financial burden on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts.

Beginning for the 2023 benefit year, we are proposing to allow state regulators to request a reduction in the calculation of risk adjustment transfers under the state payment transfer formula for up to 3 years. HHS would reserve the right to require states with approved multi-year reduction requests to submit supplemental evidence in any subsequent year of the request after its initial approval, in the timeframe, form, and manner specified by HHS, and HHS would also reserve the right to terminate or modify an approved multi-year request prior to its natural expiration. We are also proposing to permit states with approved multi-year requests to withdraw their respective request before its natural expiration by notifying HHS of its requested withdrawal. HHS would require states to inform impacted issuers of any termination, modification, or withdrawal of an approved multi-year reduction request.

Allowing multi-year state flexibility requests would lead to a reduction in burden associated with this requirement for states who elect to submit such requests. In the 2019 Payment Notice, we estimated that it would take a business operations specialist 32 hours to prepare an annual state flexibility request and 16 hours for a senior manager to review the request and transmit it electronically to HHS, for a total burden of 48 hours. The total burden over 3 years would be 144 hours. For states submitting multi-year requests, we estimate that it would take a business operations specialist 64 hours (at a rate of $77.14 per hour) to prepare the request and 32 hours for a senior manager (at a rate of $118.30 per hour) to review the request and transmit it electronically to HHS. We estimate that each state seeking a multi-year reduction request would incur a total burden of 96 hours at a cost of approximately $8,723 to comply with this reporting requirement (64 hours for the business operations specialist and 32 hours for the senior manager). If HHS requests supplemental evidence from a state to support the continued application of its request, we estimate that the state would incur a cost of approximately $1,090 (8 hours for the business operations specialist at an hourly wage of $77.14 and 4 hour for the senior manager at an hourly wage of $118.30). We estimate that a state withdrawal of a previously submitted request would impose minimal additional cost of approximately $118 on the state associated with a senior official from the State Department of Insurance submitting a withdrawal request to HHS and informing impacted issuers of the withdrawal (equivalent to 1 hour for a senior manager at an hourly wage rate of $118.30). Each state that submits a multi-year request would experience a cost reduction of approximately $4,361 over a period of 3 years (our estimate of a state's cost savings would be reduced to approximately $3,271 if HHS requests supplemental evidence from the state one time over a period of 3 years). Although we are unable to precisely estimate the number of states that would make these requests, we expect that no more than 5 states would make these requests annually.[248] For 5 states, the total reduction in burden would be 240 hours with a cost reduction of approximately $21,806 (less if HHS requests supplemental evidence). We seek comment on this estimated burden reduction.

We are proposing to provide more clarity regarding audits and compliance reviews of issuers of risk adjustment covered plans through proposed amendments to § 153.620(c). Issuers being audited under the risk adjustment program would be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. We are also proposing to codify our authority to recoup risk adjustment (including high-cost risk pool) payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with risk adjustment program (including high-cost risk pool) audits would take 120 hours by a business operations specialist (at a rate of $77.14 per hour), 40 hours by a computer systems analyst (at a rate of $92.46 per hour), and 20 hours by a compliance officer (at a rate of $70.06 per hour) per issuer per benefit year. The cost per issuer would be approximately $14,356. While the number of issuers participating in the risk adjustment program varies per benefit year, (for example, there were 751 issuers participating in the risk adjustment program for the 2016 benefit year), HHS only intends to audit a small percentage of these issuers, roughly 30–60 issuers per benefit year. Depending on the number of issuers audited each year, the total cost to issuers being audited would be between $430,692 and $861,384, with an average annual cost of approximately $646,038.

We are proposing to increase the materiality threshold for EDGE discrepancies, beginning in the 2020 benefit year, so that HHS may only take action if the amount in dispute is equal to or exceeds $100,000 or one percent of the total estimated transfer amount in the applicable state market risk pool, whichever is less. As a result of this proposal, some discrepant issuers

[248] To date, only one state (Alabama) has pursued this flexibility.

would no longer be charged for their EDGE data error. In addition, issuers in the same state market risk pool as the discrepant issuer would not receive positive adjustments to their risk adjustment transfers. This is because HHS's process for addressing material EDGE data discrepancies is to recalculate the dollar value of any difference in risk adjustment transfers, charge the discrepant issuer for the difference, and compensate the issuers who were harmed by the amount of that calculation in order or balance the market. Based on analysis of discrepancies from prior years' data, payments to these issuers are occasionally as low as $1.00 and typically represent a fraction of one percent of the issuer's overall transfers in the state market risk pool for the applicable benefit year. We anticipate that the proposal would have a minimal impact on regulatory burden. There might be a slight reduction in administrative burden to some issuers who currently report, and receive adjustments for, EDGE discrepancies that are less than a fraction of total state market risk pool transfers.

4. Audits of Reinsurance-Eligible Plans (§ 153.410(d))

We are proposing to provide more clarity regarding audits and compliance reviews of reinsurance-eligible plans through proposed amendments to § 153.410(d). Issuers being audited under the reinsurance program would be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. We are also proposing to codify our authority to recoup reinsurance payments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with reinsurance program audits would take 120 hours by a business operations specialist (at a rate of $77.14 per hour), 40 hours by a computer systems analyst (at a rate of $92.46 per hour), and 20 hours by a compliance officer (at a rate of $70.06 per hour) per issuer per benefit year. The cost per issuer would be approximately $14,356. There were 557 issuers participating in the reinsurance program for the 2015 and 496 issuers participating in the reinsurance program audits for the 2016 benefit year; however, HHS would only audit a small percentage of these issuers, roughly 30–60 issuers per benefit year. Depending on the number of issuers audited each year, the total cost to issuers being audited would be between $430,692 and $861,384, with an average annual cost of approximately $646,038.

5. Risk Adjustment Data Validation (§ 153.630(g))

In this proposed rule, we are proposing to codify two previously-established exemptions from HHS–RADV under § 153.630(g). These exemptions apply when the issuer only has small group carryover coverage for the applicable benefit year or when an issuer is in the sole issuer in the state market risk pool for the applicable benefit year (and did not participate in another risk pool with other issuers for that benefit year). Under these exemptions, these issuers are not be required to complete HHS–RADV for the given benefit year, and therefore, they would have a decreased administrative burden. However, given that these exemptions are limited to issuers exiting all markets in a state and issuers who are sole issuers in all markets in a state, we estimate that 13 issuers would be exempt from HHS–RADV for a given benefit year under these exemptions. We further note that these exemptions are not establishing new exemptions; instead, the proposed amendments to § 153.630(g) would simply further codify existing policies.

We also propose to change the HHS–RADV collections timeline from the timeline finalized in the 2020 Payment Notice in response to stakeholder feedback. Under the proposed timeline, we would implement the collection of HHS–RADV charges and disbursement of payments in the calendar year in which HHS–RADV results are released. We do not believe this proposal would change the administrative burden previously estimated as we understand that the majority of states and issuers follow a timeline that aligns more closely with the one proposed in this rulemaking and few pursued the flexibility provided under the timeline finalized in the 2020 Payment Notice.

6. Direct Enrollment (§§ 155.205, 155.220, and 155.221)

a. Enhanced Direct Enrollment Website Translations

We propose to allow QHP issuers and web-brokers participating in the FFE EDE program additional time to come into compliance with the website content translation requirements in §§ 155.205(c)(2)(iv)(B) and (C) for the website content added to their websites to participate in the FFE EDE program. Specifically, we propose for a QHP issuer or web-broker participating in the FFE EDE program to have 12 months from the date the QHP issuer or web-broker begins operating its EDE website in the relevant state to translate website content added to their websites to participate in the FFE EDE program according to the requirements in §§ 155.205(c)(2)(iv)(B) and (C). This would not absolve QHP issuers and web-brokers from translating website content subject to the requirements in §§ 155.205(c)(2)(iv)(B) and (C)[249] that is unrelated to their participation in the FFE EDE program. For example, a QHP issuer's or web-broker's implementation of the Exchange eligibility application on its website for purposes of participation in the FFE EDE program would be considered content added to its website to participate in the FFE EDE program and would be afforded the additional time for translation into applicable languages. However, QHP issuer website content subject to the § 155.205(c)(2)(iv)(C) requirements, such as Summaries of Benefits and Coverage or provider directories, would not be afforded additional time for translation into applicable languages. Similarly, website content related to a web-broker's participation in Classic DE that is subject to the § 155.205(c)(2)(iv)(C) requirements, such as plan selection pages displaying QHPs, would not be afforded additional time for translation into applicable languages beyond the one year after the web-broker has been registered with the Exchange. We believe that providing QHP issuers and web-brokers participating in the EDE program with additional time to come into compliance with the website content translation requirement for the website content added to their websites to participate in the FFE EDE program would be warranted given the significant resources associated with obtaining approval to participate in the FFE EDE program generally. Given the significant cost of third-party EDE audit requirements, providing additional time to QHP issuers and web-brokers participating in the FFE EDE program to complete website translations of website content added to their websites to participate in the FFE EDE program would provide an incentive for such entities to enter markets where there is

[249] See ''Guidance and Population Data for Exchange, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250,'' March 30, 2016. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Language-access-guidance.pdf.*

a significant number of LEP individuals, while also ensuring that website content would be accessible for individuals with LEP within a reasonable period of time. We are of the view that this flexibility would enable interested QHP issuers and web-brokers participating in the EDE program to test the market before incurring additional translation costs, which would enable smaller QHP issuers and web-broker entities to compete more effectively. Therefore, affording this additional time for translation of EDE-specific website content should reduce the burden on QHP issuers and web-brokers, at least for their first year of operations as an EDE entity in a state where the §§ 155.205(c)(2)(iv)(B) and (C) requirements apply.

b. Navigator and Certified Application Counselor Use of Web-Broker Websites

We propose to permit, but not require, assisters in FFEs and SBE–FPs to use web-broker non-Exchange websites to assist consumers with QHP selection and enrollment, provided the non-Exchange website meets certain conditions and to the extent permitted by state law. Web-brokers have developed innovative tools to support consumers shopping for QHP coverage through their non-Exchange websites for both Classic DE and EDE that assisters and the consumers they assist may find helpful when shopping for and enrolling in QHPs offered through Exchanges. In addition, some web-brokers have expressed interest in leveraging assisters' expertise in navigating more complex enrollment cases to provide additional support to the consumers they serve. At the same time, assisters have expressed a desire to obtain access to an improved consumer experience by leveraging innovative and unique consumer assistance tools and display features many web-brokers have developed for Classic DE and EDE. Additionally, some assisters have expressed a desire to have access to real-time information on the status of submitted applications and enrollments that is available through EDE to more effectively assist consumers. Although we are not proposing to require web-brokers develop assister portals for their non-Exchange websites, we recognize that some web-brokers may consider developing such portals to enable assisters to gain easy access to real-time information for each of the consumers they assist using the web-broker's non-Exchange website, similar to portals some web-brokers have already developed for affiliated agents and brokers who have entered into arrangements to access the web-broker's non-Exchange website. If the web-broker's non-Exchange website meets applicable requirements, we want to encourage this type of innovation to improve the experience for assisters and the consumers they assist with shopping for and enrolling in QHPs offered through an Exchange.

We are proposing several amendments to § 155.220 to capture new flexibility for assisters in FFE and SBE–FP states to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances and to the extent permitted by state law. This proposed flexibility would extend to both Classic DE and EDE websites that web-brokers may offer to assist consumers in FFE and SBE–FP states. We propose new § 155.220(c)(3)(iii)(A) to require web-broker websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), for such websites to be eligible for use by assisters when otherwise permitted under state law. We note that web-brokers may obtain all QHP information they would be required to display in FFEs and SBE–FPs for assisters to be permitted to use their websites by integrating with the FFEs' Marketplace API. For FFEs and SBE–FPs, we are considering adoption of an optional annual certification process for web-brokers that would be integrated into the existing annual web-broker registration process, or could occur during another time of year, during which a web-broker could be certified by the Exchange by attesting to its compliance with the requirements proposed in § 155.220(c)(3)(iii)(A). We propose to capture this optional annual certification process at new proposed § 155.220(c)(3)(iii)(B). We are also considering maintaining a public list of certified web-brokers in FFEs or SBE–FPs, so that assisters would be able to more easily identify web-broker websites they might seek to use in FFEs and SBE–FPs, when such arrangements are permitted under state law. The proposed amendments to § 155.220(c)(3)(iii)(A) would also provide that if a web-broker website does not facilitate enrollment in all QHPs it would be required to identify to consumers the QHPs, if any, for which the web-broker website does not facilitate enrollment by prominently displaying a standardized disclaimer provided by the Exchange, in a form and manner specified by the Exchange, stating that the consumer can enroll in such QHPs through the Exchange website, and display a link to the Exchange website. We anticipate issuing further guidance on the form and manner in which the disclaimer should be displayed so that it would be clearly associated with any QHPs for which the web-broker does not facilitate enrollment. We are considering whether the disclaimer or a link to the disclaimer should replace the link or other mechanism the web-broker would otherwise display to allow a consumer to proceed with selecting and enrolling in a QHP, or whether the disclaimer should be displayed in some other fashion. This proposal would not require a web-broker to modify its website unless it wishes for assisters to be able to use its website. If a web-broker chooses to leverage this flexibility, there may or may not be an associated burden. For example, some web-brokers are already displaying all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1), and may already facilitate enrollment in all QHPs. For such web-brokers, there would be no website modifications required to add QHP information or to display a disclaimer and therefore assisters would be permitted to use those web-broker websites if this policy were finalized with no actions required by the web-broker. In other cases, web-brokers might need to update their websites to add QHP information consistent with the requirements of § 155.205(b)(1), or might need to add a disclaimer if the web-broker does not facilitate enrollment in all QHPs to identify to consumers the QHPs for which the web-broker website does not facilitate enrollment. In general, we expect this proposal would add little to no new burden for existing web-brokers, because the web-brokers most likely to take advantage of this flexibility are probably those that already have websites that meet the requirements proposed at new § 155.220(c)(3)(iii) or can meet those requirements with minimal updates to their websites.

c. QHP Information Display on Web-Broker Websites

We propose to provide flexibility to web-brokers regarding the information they are required to display on their non-Exchange websites for QHPs in certain circumstances. In new proposed § 155.220(n), we propose to establish an exception to the web-broker display requirements captured at § 155.220(c)(3)(i)(A) and (c)(3)(i)(D). At new proposed § 155.220(n), we propose certain flexibilities regarding display of QHP information if a web-broker's non-

Exchange website does not support enrollment in a QHP. This situation could occur if the web-broker does not have an appointment with a QHP issuer and therefore is not permitted under state law to enroll consumers in the coverage offered by that QHP issuer. In such circumstances, we propose that the web-broker's non-Exchange website would not be required to provide all the information identified under § 155.205(b)(1). Instead, web-brokers would be required to display the following limited, minimum information for such QHPs: Issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information. To take advantage of this new proposed exception, we also propose that the web-broker's non-Exchange website would be required to identify to consumers the QHPs, if any, for which the web-broker's website does not facilitate enrollment by prominently displaying the plan detail disclaimer provided by the Exchange. The plan detail disclaimer explains that the consumer can get more information about such QHPs on the Exchange website, and includes a link to the Exchange website. To more closely align the plan detail disclaimer text [250] with the intent of this proposal, we would issue further guidance slightly revising the text of the disclaimer. For example, the current disclaimer text states, in relevant part, the web-broker ''isn't able to display all required plan information about this Qualified Health Plan at this time.'' We would modify that text so that it states, in relevant part, the web-broker ''doesn't display all plan information about, and does not facilitate enrollment in, this Qualified Health Plan at this time.'' We believe this proposal strikes an appropriate balance by recognizing that web-brokers may not be permitted to assist with enrollments in QHPs for which they do not have an appointment while still providing key information about all QHPs on web-broker non-Exchange websites to allow consumers to window shop and identify whether they may want to explore other QHP options. It also would minimize burdens for web-brokers by not requiring them to build functionality and processes to display all of the required comparative information listed in § 155.205(b)(1) for those QHPs for which they do not have an appointment to sell. We believe the burden associated with this proposal would be very limited as it would largely align with our historical enforcement approach and guidance. Web-brokers that are not displaying all the QHP information required under § 155.205(b)(1) are already displaying the plan detail disclaimer, a link to the Exchange website, and the following limited details: Issuer marketing name, plan marketing name, plan type, and metal level. The one new requirement that this proposal would impose is the display of premium and cost-sharing information for all QHPs. However, premium and cost-sharing information is and has been available through the Exchange public use files and the Marketplace API for some time now, and web-brokers are familiar with those data sources to populate their websites with other QHP information. Furthermore, premium and cost-sharing information is data web-brokers already incorporate for at least some QHPs displayed on their websites. Incorporating premium and cost-sharing information for all QHPs displayed on their websites would require a minimal level of effort.

d. Web-Broker and Direct Enrollment Entity Operational Readiness Review Requirements

At § 155.220(c)(6), we propose a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's website being used to complete an Exchange eligibility application or a QHP selection. As reflected in proposed § 155.220(c)(6)(i) through (iv), HHS may request a web-broker submit a number of artifacts or documents or complete certain testing processes to demonstrate the operational readiness of its non-Exchange website. The required documentation might include operational data including licensure information, points of contact, and third-party relationships; security and privacy assessment documentation, including penetration testing results, security and privacy assessment reports, vulnerability scan results, plans of action and milestones, and system security and privacy plans; and an agreement between the web-broker and HHS documenting the requirements for participating in the applicable direct enrollment program. The required testing processes might include enrollment testing, prior to approval or at the time of renewal, and website reviews performed by HHS to evaluate prospective web-brokers' compliance with applicable website display requirements prior to approval. To facilitate testing, prospective and approved web-brokers will have to maintain and provide access to testing environments that reflect their prospective or actual production environments. We are proposing these amendments to codify in regulation existing program requirements that apply to web-brokers that participate in the FFE direct enrollment program and are captured in the agreements executed with participating web-broker direct enrollment entities and related technical guidance.[251] Some of these requirements, such as the collection of operational data, have effectively existed for many years, and so they would impose little to no new burden. The collection of security and privacy assessment documentation would be a new requirement, although historically the web-broker agreement has required web-brokers to attest to the implementation and assessment of privacy and security controls. As a result, web-brokers should have historically completed any technical implementation of the controls and should be familiar with assessment of those controls. Completion of enrollment testing would also be a new requirement, but use of the direct enrollment pathway inherently requires a web-broker's platform to be capable of processing enrollments. Therefore, the burden of testing that functionality would be very limited. Website reviews have been conducted historically and are performed by HHS, so there would be no burden to web-brokers associated with the completion of those reviews. The burden related to these proposed requirements is discussed in the Collection of Information Requirements section above.

We propose to revise § 155.221(b)(4) to add additional detail on the operational readiness requirements for direct enrollment entities. Similar to the proposed web-broker operational readiness requirement at new proposed § 155.220(c)(6), we are proposing these amendments to codify in § 155.221(b)(4) more details about the existing program requirements that apply to direct enrollment entities and are captured in the agreements executed with participating web-broker and QHP issuer direct enrollment entities. We note that these proposed requirements are in addition to the operational readiness requirements at new proposed § 155.220(c)(6) for web-brokers,

[250] See Section 5.3.2 of the ''Federally-Facilitated Exchanges (FFEs) and Federally-Facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual.'' Available at *https://www.regtap.info/uploads/library/ENR_FFEFFSHOPEnrollmentManual2020_5CR_090220.pdf.*

[251] See, for example, ''Updated Web-broker Direct Enrollment Program Participation Minimum Requirements,'' May 21, 2020. Available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2020-WB-Program-Guidance-052120-Final.pdf.*

although web-brokers may not be required to submit the documentation required under this proposal to revise § 155.221(b)(4) or they may be permitted to use the same documentation to satisfy the requirements of both operational readiness reviews depending on the specific circumstances of their participation in direct enrollment programs and the source and type of documentation.

In paragraph (b)(4), we propose to continue to require a direct enrollment entity to demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's website being used to complete an Exchange eligibility application or a QHP selection. We add new proposed paragraphs (b)(4)(i) through (v) to reflect that direct enrollment entities may need to submit or complete, in the form and manner specified by HHS, a number of artifacts of documentation or various testing or training processes. The documentation may include business audit documentation including: Notices of intent to participate including auditor information; documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and business audit reports including testing results. The required documentation may also include security and privacy audit documentation including: Interconnection security agreements; security and privacy controls assessment test plans; security and privacy assessment reports; plans of action and milestones; privacy impact assessments; system security and privacy plans; incident response plans; and vulnerability scan results. Submission of agreements between the direct enrollment entity and HHS documenting the requirements for participating in the applicable direct enrollment program may also be required. Required testing may include eligibility application audits performed by HHS. The direct enrollment entity may also be required to complete online training modules developed by HHS related to the requirements to participate in direct enrollment programs. We expect minimal new burden associated with this proposal as these requirements have historically been established through agreements EDE entities have executed with HHS, and therefore entities have completed these tasks in the past to be able to use the EDE pathway. The burden related to these proposed requirements is discussed in the Collection of Information Requirements section above.

e. Direct Enrollment Entity Plan Display Requirements

We also propose to revise § 155.221(b)(1) to require that direct enrollment entities display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and all other products, such as excepted benefits, on at least three separate website pages, with certain exceptions. This proposal would constitute a revision of a policy adopted in 2019. We anticipate this policy would provide increased flexibility and believe many direct enrollment entity websites are already designed in a manner largely consistent with this proposal, and therefore the burden associated with it would be minimal.

f. New Exchange Direct Enrollment (DE) Options

We also propose to add § 155.221(j) establish a new Exchange direct enrollment (DE) option, beginning with PY 2022, in which states could use direct enrollment technology to transition to private sector-focused enrollment pathways operated by QHP issuers, web brokers, and agents and brokers instead of a centralized front-facing eligibility and enrollment website operated by the Exchange. State Exchanges, as well as SBE–FP, and FFE states could elect to implement the DE option. The impact of the new Exchange DE option will depend on the specific Exchange model and the number of states that take advantage of the new option. The FFEs' current direct enrollment program (classic and EDE) generally reduce operational costs to the federal government while alleviating certain burdens on consumers.

This proposal may have varied impacts on consumers, and we are interested in public comments that would better help us to understand how the DE option, and an increase in the number of potential websites maintained by brokers through which consumers could shop for QHP coverage, might impact consumers and consumer behavior with respect to QHP enrollment. We also note that any operational cost increases or savings for implementation of the DE option could, in turn, affect an SBE's user fee and consumer premium costs.

Under the FFE–DE and SBE–FP–DE, CMS would be providing back end eligibility services, notice and tax form generation, the processing of data matching and special enrollment verification issues, eligibility appeals, casework, advanced customer service, enrollment reconciliation, IRS reporting, and an alternate/backup consumer-facing process (as we do today). In addition, the *HealthCare.gov* website would continue to provide standardized comparative information for QHPs offered on the Exchange.

At this time, we do not anticipate that any of the 15 current SBEs would implement the DE option, as they have to date not implemented the same direct enrollment interfaces with web brokers or other direct enrollment entities as the FFE. However, current SBEs that elect to apply for approval to implement the DE option would be responsible for meeting certain requirements for approval, in particular revising their Exchange Blueprint (Blueprint) under new proposed § 155.221(j)(1). We believe that any costs of revising the Blueprint would be nominal, as this process involves logging electronically into a CMS web interface that serves as the repository for all states' Blueprints to input additional information on updated processes and controls to manage the new DE program. However, we seek comment on the burden associated with this activity and note that the Blueprint is currently approved under the PRA under OMB Control Number 0938–1172.

For states seeking to transition to a SBE for future plan years in order to utilize the new Exchange DE option, we anticipate that start-up costs would be similar to those associated with recent transitions to the SBE model, including any costs associated with the completion of the Blueprint. SBEs would complete the Blueprint in the same manner and would be required to meet all required minimum functions of an Exchange. In terms of implementation costs, these states could realize savings by virtue of not having to build the consumer-facing website to handle the consumer traffic that it would handle if it were the single point of enrollment, instead relying on direct enrollment entities to provide the majority or all of the enrollment functionality. However, those may be relatively lower costs than the costs associated with building the back-end Exchange eligibility platform to complete eligibility determinations, along with the applicable connections required to the Federal Data Services Hub for performing eligibility verifications, as well as connections to the respective state Medicaid agency for coordinating Medicaid and CHIP eligibility determinations. Based on recent state transitions to the SBE

model, the design, development, and implementation costs for an Exchange depend on a number of factors. Recent design, development, and implementation costs have ranged from $4 million for a smaller state, to almost $24 million for a larger state. As no SBE to date has implemented direct enrollment, however, we are not able to provide accurate cost estimates in this regard. States may also be able to use existing federal DE partners who are fully compliant with federal operational requirements to provide administrative savings. Any operational cost increases or savings could, in turn, affect an SBE's user fee and premium costs.

We do anticipate that an SBE electing the Exchange DE option would have increased operational costs for monitoring and oversight of the DE entities, as well as for maintaining and managing the individual interfaces and transactions with each DE entity. However, any savings achieved through a decrease in call center volume or other consumer supports due to DE partners assisting consumers with enrollment would offset any increased operational supports. Any operational savings could, in turn, affect an SBE's user fee.

We also anticipate that the DE option could have impacts on web-brokers and issuers. With respect to web brokers, costs may be incurred if there are new entrants to the DE market or if existing DE participants expand into new markets. We presume that web brokers will rationally only enter the market or expand into new markets if it the benefits exceed the costs. Web brokers may enter into fee-based arrangements with issuers, or possibly new economic or legal arrangements with states, that help to offset the costs of the DE services provided. Web brokers may also assume costs associated with the optional certification process. Issuers will be impacted by adjustments in user fees, and may have an incentive to promote direct enrollment if user fees are lower under the DE option, and those savings exceed the new costs of arrangements with web brokers. Issuers may also be impacted if the DE option leads to shifts in consumer enrollment patterns, such as movement from a QHP offered by one issuer to a QHP offered by another issuer.

We also do not anticipate that HHS will have any increased costs associated with monitoring and oversight of the SBE–DEs. We note that changes in premiums may have downstream impacts on federal payments of PTCs.

We seek comment on this proposal, including any additional consumer, state and SBE, HHS, issuer, web-broker, or other costs, benefits or transfers that should be considered. We also seek data and information that would help us to quantify the potential impacts associated with this proposal.

7. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)

As discussed previously in the preamble, as for benefit years 2020 and 2021, we will not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4) for benefit year 2022, and we propose to amend § 155.320(d)(4) to reflect that the requirement will not be applied in plan years 2021 and 2022. 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 paragraph (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 sample enrollees have been determined by HHS to have received APTC/CSRs inappropriately. We estimate the annual costs to conduct sampling on a statistically significant sample size of approximately 1 million cases to be approximately $6 million to $8 million for the Exchanges using the Federal platform and State Exchanges that operate their own eligibility and enrollment platforms. This estimate includes operational activities such as noticing, inbound and outbound calls to the Marketplace call center, and adjudicating consumer appeals. We estimate that the total annual cost for the Exchanges using the Federal platform and the 15 State Exchanges operating their own eligibility and enrollment platform in 2022 would be $113 million. Relieving Exchanges of the requirement to conduct sampling for benefit year 2022 would therefore result in total savings of approximately $113 million. We seek comment on this estimate.

8. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for APTC

We propose to add a new paragraph at § 155.420(a)(4)(ii)(C) to allow Exchange enrollees and their dependents who become newly ineligible for APTC in accordance with paragraph (d)(6)(i) or (ii) of this section to enroll in a QHP of a lower metal level. We anticipate that this proposal would help impacted enrollees' ability to maintain continuous coverage for themselves and for their dependents in spite of losing a potentially significant amount of financial assistance to help them purchase coverage. For example, an enrollee impacted by an increase to his or her monthly premium payment could change to a bronze-level plan, or to catastrophic coverage if they are otherwise eligible. Relatedly, this proposal may benefit the individual market risk pool by encouraging healthy individuals to maintain continuous coverage. Currently, an enrollee who loses APTC eligibility has only two choices: Paying the full premium or terminating his or her coverage. Healthy individuals who lose APTC may be more likely to terminate coverage due to increased premium liability, while enrollees who have one or more medical conditions will be incentivized to maintain coverage in spite of the additional expense. This proposal would serve to facilitate continuous coverage of healthy individuals by giving them the ability to enroll in a new plan with a lower premium, thereby supporting a healthier risk pool.

Regardless, we believe that this change would not have a negative impact on the individual market risk pool, because most applicable enrollees would be seeking to change coverage based on financial rather than health needs. However, as discussed earlier in the preamble, we seek comment on whether there are concerns about adverse selection risk with permitting newly unsubsidized enrollees to change to any plan of a lower metal level to help them maintain coverage (for example, permitting an individual to change from a gold plan to a bronze plan), or whether this risk would be significantly lower if we only permit an enrollee to change to a plan one metal level lower than their current QHP. We also request comment from issuers on whether there are concerns about impacts such as experiencing a decrease in premium receipts from enrollees who opt to change to a lower-cost plan, or whether they view adverse selection as a possibility. As discussed in more detail earlier in the preamble, we also acknowledge that enrollees may lose APTC eligibility and qualify for a special enrollment period due to their APTC loss for a reason other than a change in household income or tax family size. We seek comment on whether stakeholders have concerns with this possibility, as well as on how HHS can help ensure that enrollees who lose APTC because of failure to provide information to the Exchange to confirm their APTC eligibility can understand and take action on steps needed to do

so, even if they also have the flexibility to change to a plan of a lower metal level.

We recognize, as further discussed in preamble, that changing to a new QHP mid-plan year may cause enrollees to incur additional out of pocket costs, as a new QHP selection typically resets the enrollee's deductible and other accumulators. We believe that Exchange enrollees who lose APTC eligibility are best able to weigh the trade-off between reset accumulators and maintaining an affordable monthly premium, and losing coverage altogether. Enrollees who qualify to make a new plan selection for an applicable special enrollment period already must consider this question. However, we request comment on whether this proposal would increase the risk that consumers will change plans without taking into account potential disadvantages, and on strategies to help mitigate this risk, such as consumer education.

Additionally, this proposal would impose a cost to Exchanges that have implemented plan category limitations, because it would require the use of financial and staff or contractor resources to make a change to application and plan selection system logic to permit applicable enrollees and dependents to change to a lower metal level plan after having previously restricted them to plans of their current metal level. Therefore, we solicit comments on the extent to which Exchanges would experience burden due to this proposed change, and we also seek comment on whether we should exempt the special enrollment periods at § 155.420(d)(6)(i) and (ii) due to becoming newly ineligible for APTC from plan category limitations altogether to help to mitigate this burden, or whether such a change would significantly increase risk for adverse selection.

Finally, because it represents a change to current system logic, this proposal might impose some burden on FFE Direct Enrollment and Enhanced Direct Enrollment partners. We solicit comment on this matter, as well as more generally, on the impact this proposal.

b. Special Enrollment Period—Untimely Notice of Triggering Event

We anticipate that the proposed amendments related to qualified individuals who do not receive timely notice of a triggering event and otherwise are reasonably unaware that a triggering event occurred would provide certain consumers a pathway to maintain continuous coverage, which would have an overall positive impact on the risk pool and would benefit consumers. Consumers would benefit from being able to maintain continued access to coverage and health care. We recognize the possibility of some minor adverse selection risk given that consumers with known health issues may be more likely to request a retroactive effective date than healthy consumers. However, we expect this risk to be very limited as the proposal only permits individuals to request a retroactive effective date if they did not receive timely notice of a triggering event, and we do not expect this to happen very often.

We expect that Exchanges and Direct Enrollment partners might incur minor costs to update consumer messaging and processes to administer this proposal. State Exchanges that currently do not have this policy and issuers offering off-Exchange plans would incur minor costs to implement this proposal. We seek comment on this proposal, including any costs, benefits or burdens associated with this proposal.

c. Cessation of Employer Contributions to COBRA as Special Enrollment Period Trigger

We anticipate that the proposed amendments regarding special enrollment period eligibility for qualified individuals whose employers completely cease payment of their portion of COBRA continuation coverage premiums would provide clarity regarding a policy that has been operationalized on *HealthCare.gov*. We believe that these amendments would benefit direct enrollment partners and employers by providing clarity regarding special enrollment period eligibility. In addition, consumers who would have otherwise lost coverage due to an increase in the cost of their COBRA continuation coverage would benefit from continuity of coverage and access to healthcare.

Because this special enrollment period has already been available to individuals enrolling in a QHP on *HealthCare.gov*, we do not anticipate that these amendments would have any negative impact on the risk pool, nor would they increase costs for direct enrollment partners or *HealthCare.gov.* However, we do anticipate that State Exchanges that do not have this policy, as well as issuers who operate off-Exchange plans, would incur costs to implement this proposal. We seek comment on this proposal, including any associated costs, benefits or burdens.

d. Special Enrollment Period Verification (§ 155.420)

We do not anticipate that revisions to § 155.420 would impose regulatory burden or costs on the Exchanges using the federal platform. We anticipate that this proposal would have a positive impact on program integrity by verifying eligibility for special enrollment periods. Increasing program integrity through this proposal could contribute to keeping premiums low and therefore, protect taxpayer dollars. However, FFE, SBE–FPs, and most State Exchanges already conduct special enrollment period verification in accordance with this proposal, so premium impact would likely be very minimal.

We anticipate this proposal would moderately increase regulatory burden on existing State Exchanges, along with FFE and SBE–FP states currently transitioning to establishing State Exchanges, that do not currently conduct special enrollment period verification for at least 75 percent of enrollments for newly enrolling consumers enrolling through special enrollment periods. A majority of State Exchanges currently conduct SEP verification for the same SEP types for which the FFEs currently conduct SEP verifications, with some State Exchanges conducting SEP verifications for additional SEP types, while 4 State Exchanges currently conduct SEP verifications for only one type of SEP. Those 4 State Exchanges include those in the District of Columbia, Maryland, Rhode Island, and Vermont. State Exchanges bear the full cost of the SEP verification activities they conduct. All the State Exchanges that currently conduct SEP verifications in the same manner as the FFEs do are verifying 75 percent or more of their respective SEP enrollments. This includes the State Exchanges with the highest SEP enrollment volume, such as the California and New York Exchanges. For the 4 State Exchanges that conduct SEP verifications for only one type of SEP, that SEP type consistently represents about 60 percent of all SEP enrollments across each of these four State Exchanges.

Based on the implementation of pre-enrollment special enrollment period verification in the Exchanges using the federal platform, we estimate that the overall one-time cost of implementing pre- or post-enrollment SEP verification by an Exchange would be approximately $12 million. Therefore, we estimate that the total cost for the 4 existing State Exchanges that currently do not conduct special enrollment period verification for at least 75 percent of enrollments for

newly enrolling consumers enrolling through special enrollment periods would be $48 million in order to comply with this new requirement for PY 2024. Additionally, there would be costs for at least 1 FFE state and 4 SBE–FP states that are transitioning to, or have notified us that they intend to transition to, establishing State Exchanges on or after the 2021 plan year to implement this new requirement. We estimate that total implementation costs for these 5 states would be $60 million. Including both categories of State Exchanges, total costs for State Exchanges to implement this new requirement are estimated to be $108 million. We assume these costs will be incurred in the years 2021–2023.

There also would be an increase in ongoing costs for 5 existing State Exchanges due to an increase in the number of special enrollment period enrollments for which they must conduct verification. We estimate that the total increase in ongoing costs for these 5 existing State Exchanges to comply with this requirement would be $2.8 million for 2024 and 2025. We estimate that the Exchanges using the federal platform would not incur any increase in costs to comply with this requirement. In addition, the 1 FFE state and 4 SBE–FP states that are transitioning to, or have informed us that they intend to transition to, establishing State Exchanges, would incur costs to comply with this requirement instead of the FFEs, estimated to be $3.5 million for 2024 and 2025, which would result in a transfer from the State Exchanges to the FFEs. We do not anticipate this proposal would increase regulatory burden or costs on issuers.

9. FFE and SBE–FP User Fees (§ 156.50)

We are proposing a lower FFE user fee rate of 2.25 percent for the 2022 benefit year, which is lower than the 3.0 percent FFE user fee rate finalized for 2021 benefit year. We also propose to lower the SBE–FP user fee rate to 1.75 percent for the 2022 benefit year from the 2.5 percent SBE–FP user fee rate we finalized for the 2021 benefit year. We are proposing a FFE–DE and SBE–FP–DE user fee rate of 1.5 percent for the 2023 benefit year. Subject to HHS approval, states could elect to use the FFE–DE or SBE–FP–DE options. Based on our estimated costs, enrollment (including anticipated transitions of states from the FFE and SBE–FP models to either the SBE–FP or State Exchange models), premiums for the 2021 and 2022 benefit years, and proposed user fee rates, we are estimating FFE and SBE–FP user fee transfers from issuers to the federal government would be lower by $270 million compared to those estimated for the prior benefit year. Costs could be shifted to approve direct enrollment partners (including QHP issuers) that states elect to use, so there may not actually be any cost savings on the part of issuers in states that elect the FFE–DE or SBE–FP–DE options. As such, there might not be an incentive for issuers in states that have elected the FFE–DE or SBE–FP DE option to adopt these models solely as a result of the lower user fee rate. While there would be reduced transfers to the federal government in states that elect the FFE–DE or SBE–FP–DE options, we expect that available user fee collections from current and prior years would be sufficient to fund Exchange operations through 2023 at the proposed 2023 benefit year user fee rates. We expect that the proposed adoption of the FFE–DE and SBE–FP–DE user fee rates and the proposed decreases in the FFE and SBE–FP user fee rate would reduce transfers to the federal government by $400 million in 2023.

10. Provisions Related to Cost Sharing (§ 156.130)

The PPACA 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 set forth in this proposed rule the reductions in the maximum annual limitation on cost sharing for silver plan variations for the 2022 benefit year. 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 2022 maximum annual limitation on cost sharing for self only coverage of $9,100. We do not believe the proposed changes to the maximum annual limitation on cost sharing or the reductions in this parameter for silver plan variations would result in a significant economic impact.

Furthermore, we propose the premium adjustment percentage for the 2022 benefit year. 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 PPACA: 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) of the Code. We believe that the premium adjustment percentage of 1.4409174688 based on average per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance) is well within the parameters used in the modeling of the PPACA, and we do not expect that these proposed updated values would alter CBO's May 2020 baseline projections.

We also propose that beginning with the 2023 benefit year, we would publish the premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitations on cost sharing, and required contribution percentage in guidance in January of the calendar year preceding the benefit year to which the parameters are applicable, unless HHS is changing the methodology in which case we would do so through the applicable HHS notice of benefit and payment parameters. This proposal affects only the timing and method by which these parameters are released and would provide issuers with additional time for plan design and rate setting.

11. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295) and PBMs (§ 184.50)

As part of the PPACA, Congress passed section 6005, which added section 1150A to the Act, requiring a PBM under a contract with a QHP offered through an Exchange established by a state under section 1311 of the PPACA [252] to provide certain prescription drug information to the QHP and to Secretary at such times, and in such form and manner, as the Secretary shall specify. Section 1150A(b) of the Act addresses the information that a QHP issuer and their PBM must report. Section 1150A(c) of the Act requires the Secretary to keep the information reported confidential and specifies that the information may not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs for certain purposes.[253]

[252] This includes an FFE, as a Federal Exchange may be considered an Exchange established under section 1311 of the PPACA. *King* v. *Burwell,* 576 U.S. 988 (2015).

[253] The purposes are: As the Secretary determines to be necessary to carry out section 1150A or part

On January 1, 2020 [254] and on September 11, 2020,[255] we published notices in the **Federal Register** and solicited public comment on the burden related to the collection of information required by section 1150A of the Act. In those information collections and in this proposed rule, we fulfill this statutory requirement with the goal of imposing the least amount of burden possible while collecting data that would be usable to ensure increased transparency on prescription drug coverage in QHPs.

For example, to reduce overall burden, we seek to collect data directly from PBMs that contract with QHPs directly, rather than require QHP issuers to serve as a go-between their PBM and CMS.[256] This approach would reduce overall burden on QHP issuers and would place the onus to report data on those entities that QHP issuers have already entrusted to oversee and manage their prescription drug line of business.

These information collections also explained how we utilize the reporting paradigm currently used by CMS' Direct and Indirect Remuneration (DIR) reporting requirement which collects, in part, the data required by section 1150A(a)(1) of the Act from Prescription Drug Plan sponsors of a prescription drug plan and Medicare Advantage organizations offering a Medicare Advantage Prescription Drug Plan under part D of title XVII. We noted our intention to utilize the DIR reporting mechanisms only to the extent authorized solely by section 1150A(a)(2), explaining our understanding that DIR reporting is not authorized by section 1150A alone.[257] Usage of these existing CMS reporting paradigms ensures minimal impact of a new data collection on QHP issuers and PBMs, given the longstanding industry use of the DIR reporting mechanism. The payer community is familiar with fulfilling the DIR reporting requirement. Therefore, we believe replicating that collection to the greatest degree would enable reporters to implement this data collection with minimal relative burden.

12. Audits of APTCs, CSRs, and User Fees (§ 156.480(c))

We are proposing to provide more clarity around the APTC, CSR, and user fee program audits and to establish authority for HHS to conduct compliance reviews to assess compliance with Federal APTC, CSR, and user fee standards through proposed amendments to § 156.480(c). Issuers being audited under the APTC, CSR, and user fee programs would be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. We are also proposing to codify our authority to recoup APTC, CSR payments, and user fee overpayments if they are not adequately substantiated by the data and information submitted by issuers during the course of the audit.

We anticipate that compliance with APTC, CSR, and user fee program audits would take 120 hours by a business operations specialist (at a rate of $77.14 per hour), 40 hours by a computer systems analyst (at a rate of $92.46 per hour), and 20 hours by a compliance officer (at a rate of $70.06 per hour) per issuer per benefit year. The cost per issuer would be approximately $14,356. While the number of QHP issuers participating in the APTC, CSR, and user fee programs vary per benefit year (for example, there were 561 QHP issuers participating in the programs for the 2019 benefit year), HHS only intends to audit a small percentage of these issuers, roughly 30–60 issuers per benefit year. Depending on the number of issuers audited each year, the total cost to issuers being audited would be between $430,692 and $861,384, with an average annual cost of approximately $646,038.

13. Quality Rating System (§ 156.1120) and Enrollee Satisfaction Survey System (§ 156.1125)

In this proposed rule, we seek comment on removing one or more levels of the QRS hierarchy, which is a key element of the QRS framework that establishes how quality measures are organized for scoring, rating and reporting purposes. We also propose to make the full QHP Enrollee Survey results publicly available in an annual PUF. We anticipate that both changes would benefit consumers and QHP issuers by increasing transparency and availability of QHP survey data through publication of a nationwide PUF, and simplifying the QRS scoring hierarchy to improve understanding of QRS quality rating information and alignment with other CMS quality reporting programs. Neither refinement would alter the data collection and reporting requirements for the QRS and QHP Enrollee Survey because QHP issuers are already required to report all data needed to support a QHP Enrollee Survey PUF and simplified QRS hierarchy. Therefore, these proposed refinements would create no additional cost or burden for QHP issuers.

14. Medical Loss Ratio (§§ 158.103, 158.130, 158.240, and 158.241)

In this proposed rule, we propose to amend § 158.103 to establish the definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes pursuant to § 158.140(b)(1)(i). We do not expect this proposed clarification to change the result of the regulatory impact analysis previously conducted for the HHS Notice of Benefit and Payment Parameters for 2021 with respect to the requirement that issuers deduct from MLR 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 a PBM or other entity providing pharmacy benefit management services to the issuer.

We also propose that issuers that choose to provide temporary premium credits to consumers during a declared PHE in 2021 and beyond when permitted by HHS must account for these credits as reductions to premium for the applicable months when reporting earned premium for the applicable MLR reporting year. Although we do not know how many states will permit issuers to provide temporary credits to reduce premiums or how many issuers will elect to do so, for purposes of this analysis, we previously estimated in the interim final rule on COVID–19 (85 FR 54820) that approximately 40 percent of issuers offering individual, small group or merged market health insurance coverage will provide these premium credits to reduce the premiums charged to enrollees to support continuity of coverage during the PHE for COVID–19. We do not estimate a change to the cost or burden previously estimated in that final rule, and anticipate that that regulatory impact estimate would

D of title XVIII; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; and, to States to carry out section 1311 of the PPACA.

[254] 85 FR 4993 through 4994.

[255] 85 FR 56227 through 56229.

[256] Under this interpretation, QHP issuers would be required to report data directly to CMS only when the QHP issuer does not contract with a PBM to administer their drug benefit. As we explained in the notices in the **Federal Register** and in this proposed rule, we are not aware of any QHP issuer which does not contract with a PBM to administer its drug benefit. Thus, we believe that there is no associated burden or regulatory impact for QHP issuers that do not contract with a PBM.

[257] Except for PBM spread amount aggregated to the plan benefit package level, section 1150A imposes no additional reporting requirements for entities subject to DIR reporting. See 77 FR 22094.

extend to 2021 and beyond, if the provisions in this proposed rule are adopted and there are declared PHEs in the future. Although we do not know the number of issuers that would provide these temporary credits or the amount of premium credits that issuers may elect to provide, for purposes of this estimate we assume that such premium credits would on average constitute approximately 8 percent of total annual premium (equivalent to one month of premium), as previously estimated in the final rule. Because the MLR calculation uses three consecutive years of data, there may be additional rebate decreases in subsequent years, although the impact on rebates might be smaller as issuers would likely account for the premium relief provided to enrollees through these premiums credits at the time they develop premium rates for the 2022 benefit year and other future benefit years.

We also propose to add a new § 158.240(g) to explicitly allow issuers to prepay a portion or all of their estimated MLR rebates to enrollees for a given MLR reporting year, and to establish a safe harbor allowing such issuers, under certain conditions, to defer the payment of rebates remaining after prepayment until the following MLR reporting year. We additionally propose to amend § 158.241(a) to allow issuers to provide rebates in form of a premium credit prior to the date that the rules currently provide. We do not expect these proposals to have a significant quantitative impact as they would not change the rebate amounts provided by issuers to enrollees. Since it is easiest and most cost-effective for issuers to conduct rebate disbursement activities all at once, the additional rebates would generally be paid during the following year's disbursement cycle—that is, if 95 percent of rebates for 2020 was prepaid during Jan–July 2021, the remainder would be paid no later than Sept. 2022 (possibly earlier in 2022 if the issuer decides to prepay again). However, we note that there may be some increased administrative burden on issuers who owe rebates remaining after prepayment associated with good faith efforts to locate enrollees, if any, with whom they no longer have a direct economic relationship.

15. State Innovation Waivers

In this proposed rule, we propose to reference and incorporate the existing 2018 Guidance in full into the section 1332 waiver implementing regulations in order to give states certainty regarding the requirements to receive and maintain approval of a section 1332 waiver by the Departments. This rule does not propose to alter any of the requirements related to state innovation waiver applications, compliance and monitoring, nor evaluation in a way that would create any additional cost or burden for states seeking waiver approval or those states with approved waiver plans. The Departments are of the view that the increased certainty regarding the application requirements would allow states to have greater confidence that the significant time and monetary investments necessary to plan for and submit a section 1332 waiver application would not result in wasted resources and taxpayer dollars. This could help to increase state innovation, which in turn could lead to more affordable health coverage for individuals and families in states that consider implementing a section 1332 waiver program.

16. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed 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 the total number of unique commenters on last year's proposed rule will be the number of reviewers of this 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 last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed 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 proposed 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 $110.74 per hour, including overhead and fringe benefits.[258] Assuming an average reading speed, we estimate that it would take approximately 1 hours for the staff to review the relevant portions of this proposed rule that causes unanticipated burden. We assume that 245 entities will review this proposed rule. For each entity that reviews the rule, the estimated cost is approximately $110.74. Therefore, we estimate that the total cost of reviewing this regulation is approximately $27,131 ($110.74 × 245 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this proposed rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

Under part 153 of this proposed rule, we propose to recalibrate the risk adjustment models for the 2022 benefit year using 2016, 2017, and 2018 enrollee-level EDGE data. The purpose of using these data years is to ensure that the applicable benefit year's risk adjustment model coefficients can always be included in the applicable proposed and final HHS notice of benefit and payment parameters. As part of our consideration of recalibration of the risk adjustment models for the 2022 benefit year, we also considered proposing to recalibrate the risk adjustment models using the 2017, 2018, and 2019 benefit year enrollee-level EDGE data. If we had proposed that approach, we would not have been able to provide the proposed coefficients in this proposed rule and would have had to display draft coefficients only reflective of the 2017 and 2018 benefit years of enrollee-level EDGE data.

We also considered alternatives to the proposed model specification and revised enrollment duration factors to the risk adjustment models beginning with the 2022 benefit year. For example, we initially considered adding a non-linear term or HCC counts terms for all enrollees to the adult and child risk adjustment models. As described earlier in this proposed rule, we had convergence issues with the non-linear model specifications and concerns that the HCC counts terms approach posed significant gaming concerns.

In addition to the non-linear and HCC counts model specifications, we also considered alternatives to the two-stage specification and HCC interacted counts

[258] *https://www.bls.gov/oes/current/oes_nat.htm.*

model. Specifically, we tested various alternative caps for the weights based on the distribution of costs, but found the proposed caps resulted in better prediction on average. For the prediction weights, we tested various alternative forms of weights, including reciprocals of square root of prediction, log of prediction, and residuals from first step estimation, but the reciprocal of the capped predictions resulted in better predictive ratios for low-cost enrollees compared to any of the other weights.

For the interacted HCC counts factors, we tested several HCCs and considered adding and removing certain HCCs from the proposed list in Table 3. We choose the list of HCCs in Table 3 because including these HCCs most improved prediction for enrollees with the highest costs, multiple HCCs, and with these specific HCCs. For the HCC interacted counts, we also considered various alternatives to structure the interacted HCC counts, such as applying individual interacted HCC counts factors (between 1–10 based on the number of HCCs an enrollee has) to each of the selected HCCs included in the models (instead of combining all of the selected HCCs into two severe and transplant indicator groups). We choose the proposed model specifications because it would add fewer additional factors to the models without sacrificing any significant predictive accuracy.

For the enrollment duration factors in the adult risk adjustment models, we propose to replace the enrollment duration factors with monthly duration factors of up to 6 months for those with HCCs. The purpose of this proposed change is to address the underprediction of plan liability for adults with HCCs. As part of this assessment, we considered whether enrollment duration factors by market type may be warranted. However, we did not find a major distinction in market-specific incremental monthly enrollment duration factor risk scores after isolating the enrollment duration factors to enrollees with HCCs.

We considered including a requirement for states to submit and be approved for a State Innovation Waiver under section 1332 of the PPACA as part of the proposed Exchange DE options. However, nothing under the plain terms of section 1311(d)(4) the PPACA governing the functions of an Exchange requires an Exchange to host a single, consumer-facing website to receive applications or support plan shopping and selection.[259] Thus we concluded that there is no requirement in the PPACA that must be waived to allow a state to implement the DE option, and requiring states to expend taxpayer dollars to file a waiver application would be unnecessary and unduly burdensome.

We considered taking no action regarding our proposal to add a new § 155.420(a)(4)(iii)(C) in order to allow enrollees and their dependents to enroll in a new QHP of a lower metal level[260] if they qualify for a special enrollment period due to becoming newly ineligible for APTC. However, based on questions and concerns from agents and brokers, the current policy prevents some enrollees from maintaining continuous coverage because they lose a significant amount of financial assistance that would help them purchase coverage, and cannot enroll in a new, less costly QHP of a lower metal level. HHS believes this proposal is unlikely to result in adverse selection, and may improve the risk pool by supporting continued health insurance enrollment by healthy individuals who would be forced to end coverage in response to an increase in premium.

We also considered whether to propose additional flexibility to allow enrollees and their dependents who become newly eligible for APTC in accordance with section 155.420(d)(6)(i) or (ii) to enroll in a QHP of a higher metal level, because we recognize becoming newly eligible for APTC may increase the affordability of higher metal level plans for some individuals. However, we believe including this flexibility would largely exempt the special enrollment periods at paragraph (d)(6)(i) and (ii) from the rules at 155.420(a)(4)(iii), imposing risks of adverse selection by permitting individuals to change coverage levels in response to health status changes. Furthermore, while we believe the proposed flexibilities for individuals who become newly ineligible for APTC are needed in order to promote continuous coverage for individuals who can no longer afford their original plan choice, no similar affordability and continuous coverage concerns exist for enrolled consumers who gain APTC eligibility during the coverage year. Accordingly, at this time we are not proposing additional plan flexibility for enrollees who become newly eligible for APTC.

We considered taking no action regarding our proposal to add a new § 155.420(c)(5) to allow a qualified individual, dependent or enrollee that did not receive timely notice of a triggering event or was otherwise reasonably unaware that a triggering event described in § 155.420(d) occurred to select a new plan within 60 days of the date he or she knew, or reasonably should have known, of the occurrence of the triggering event. However, in some circumstances this would result in consumers, through no fault of their own, being unable to access a special enrollment period for which they were eligible. Additionally, we considered not adding new § 155.420(b)(5) to provide a qualified individual, dependent, or enrollee described in new § 155.420(c)(5) with the option for a retroactive effective date. Failing to provide the option for a retroactive effective date would necessarily result in a gap in coverage, and therefore hinder a consumer's ability to maintain continuous coverage.

We also considered limiting the applicability of the proposal to add a new § 155.420(c)(5) to a qualified individual, enrollee, or dependent who does not receive notice or become reasonably aware of the occurrence of a triggering event until more than 15 days after the triggering event. However, failing to apply the new § 155.420(c)(5) to qualified individuals, enrollees, or dependents who receive notice or become reasonably aware of the occurrence of a triggering event 15 days or less after the triggering event and eliminating the option for a retroactive effective date for those individuals would result in a gap in coverage for such individuals and hinder their ability to maintain continuous coverage.

We considered taking no action regarding our proposal to add new paragraph (v) to § 155.420(d)(1) to specify that complete cessation of employer contributions to COBRA continuation coverage is a special enrollment period triggering event. However, codifying this policy in regulation provides transparency to a long-standing interpretation of the FFEs

[259] Section 1311(d)(4)(C) of the PPACA requires only that ''[a]n Exchange shall, at a minimum . . . maintain an internet website through which enrollees and prospective enrollees of qualified health plans may obtain standardized comparative information on such plans . . . .''

[260] Section 1302(d) of the PPACA describes the various metal levels of coverage based on AV, and section 2707(a) of the PHS Act directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which includes the requirement to offer coverage at the metal levels of coverage described in section 1302(d) of the PPACA. Consumer-facing *HealthCare.gov* content explains that metal levels serve as an indicator of ''how you and your plan split the costs of your health care,'' noting that lower levels like bronze plans have lower monthly premiums but higher out of pocket costs when consumers access care, while higher levels like gold have higher monthly premiums but lower out of pocket costs to access care—see *https://www.healthcare.gov/choose-a-plan/plans-categories/.*

and SBE–FPs. Additionally, codifying this policy in regulation ensures alignment across all Exchanges and in the off-Exchange individual market.

We considered several alternatives to requiring that all Exchanges conduct special enrollment period verification for at least 75 percent of new enrollments through special enrollment periods for consumers not already enrolled in coverage through the applicable Exchange, including designating specific special enrollment period types, like Loss of Minimum Essential Coverage, that must be verified. We concluded that designating a percentage of special enrollment period enrollments that must be verified would provide Exchanges with implementation flexibility to decide the best way to conduct special enrollment period verification based on Exchange type, population characteristics, and trends. We also considered the impact of not proposing the revision requiring special enrollment period verification, but concluded that the proposed revision would have an overall positive impact on program integrity by reducing the risk of ineligible consumers enrolling in Exchange coverage through a special enrollment period.

For our proposals to revise § 156.295 and add § 184.50 to require certain prescription drug reporting, we considered, but did not yet require, the reporting of data described in section 1150A(b)(1) broken down by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medication to the general public). As mentioned above, we are aware that it is not currently possible to report such data by pharmacy type because pharmacy type is not a standard classification currently captured in industry databases or files. While we believe the imposition of this level of reporting would impose unreasonable burden at this time, we intend to begin collecting this information in the future.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (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 proposed rule, we propose standards for the risk adjustment program, which are intended to stabilize premiums and reduce incentives for issuers to avoid higher-risk enrollees. 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.[261] 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 [262] submissions for the 2019 MLR reporting year, approximately 77 out of 479 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 67 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. Therefore, we do not expect the proposed provisions of this rule to affect a substantial number of small entities.

In this proposed rule, we propose requiring certain QHP issuers or their PBMs to report certain prescription drug information to CMS. We are not aware of any QHP issuer or PBM that contracts with a QHP issuer to administer their prescription drug benefit which would be considered a ''small entity'' under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule under title XVIII, title XIX, or part B of title 42 of the Act may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. While this rule is not subject to section 1102 of the Act, we have determined that this proposed rule would not affect small rural hospitals. Therefore, the Secretary has determined that this rule would 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 one 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. Currently, 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 proposed rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications. In our view, while this proposed rule would not impose substantial direct requirement 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.

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

[261] *https://www.sba.gov/document/support--table-size-standards.*

[262] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

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. A user fee is assessed on issuers under all existing Exchange models, including State Exchanges where the user fee is assessed by the state, SBE–FPs, and the FFEs. We have solicited comment on the proposed user fee rate of 1.5 percent of monthly premiums or issuers in Exchanges that adopt the newly proposed FFE–DE and SBE–FP–DE options.

H. Congressional Review Act

This proposed 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, and has been transmitted to the Congress and the Comptroller for review. This proposed rule, if finalized as proposed, is expected to be 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 new 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 proposed rule, if finalized as proposed, is expected to be E.O. 13771 regulatory action. We estimate costs of approximately $52.45 million in 2021, cost savings of approximately $72.08 million in 2022, costs of approximately $40.92 in 2023 and annual costs of approximately $6.32 million thereafter. Thus the annualized value of costs, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, would be $4.65 million.

List of Subjects

31 CFR Part 33

Health care, Health insurance, Reporting and recordkeeping requirements, Waivers for State Innovation.

45 CFR Part 147

Age discrimination, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 150

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Age discrimination, Brokers, Civil rights, Citizenship and naturalization, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, 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, Sex discrimination, State and local governments, Technical assistance, Taxes, Women, Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Age discrimination, Alaska, Brokers, Citizenship and naturalization, Civil rights, 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, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, 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.

45 CFR Part 184

Administrative practice and procedure, Consumer protection, Health care, Health insurance, Health maintenance organization (HMO), Organization and functions (Government agencies), Prescription Drugs, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of the Treasury amends 31 CFR subtitle A as set forth below:

PART 33—WAIVERS FOR STATE INNOVATION

■ 1. The authority citation for part 33 continues to read as follows:

Authority: Sec. 1332, Pub. L. 111–148, 124 Stat. 119.

■ 2. Section 33.108 is amended by revising paragraph (f)(3)(iv) introductory text to read as follows:

§ 33.108 Application procedures.

* * * * *

(f) * * *

(3) * * *

(iv) The analyses, actuarial certifications, data, assumptions, analysis, targets and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of Health and Human Services, as applicable, with the necessary data to determine

that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with guidance published by the Secretary and the Secretary of Health and Human Services at 83 FR 53575 (Oct. 24, 2018):

* * * * *

■ 3. Section 33.120 is amended by revising paragraph (a)(1) to read as follows:

§ 33.120 Monitoring and compliance.

(a) * * * (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of Health and Human Services, as applicable, a State must comply with all applicable Federal laws, regulations, and interpretive policy statements, as well as guidance published by the Secretary and the Secretary of Health and Human Services at 83 FR 53575 (Oct. 24, 2018), unless expressly waived. A State must, within the timeframes specified in law, regulation, policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

* * * * *

■ 4. Section 33.128 is amended by revising paragraph (a) to read as follows:

§ 33.128 Periodic evaluation requirements.

(a) The Secretary and the Secretary of Health and Human Services, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with guidance published by the Secretary and the Secretary of Health and Human Services, including the *State Relief and Empowerment Waivers* guidance published on October 24, 2018, as applicable, and any terms and conditions governing the section 1332 waiver.

* * * * *

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL INSURANCE MARKETS

■ 5. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 6. Section 147.104 is amended by revising paragraphs (b)(2)(ii) and (4)(ii) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(2) * * *

(ii) In applying this paragraph (b)(2), a reference in § 155.420 (other than in §§ 155.420(a)(5) and 155.420(d)(4)) of this subchapter to a ''QHP'' is deemed to refer to a plan, a reference to ''the Exchange'' is deemed to refer to the applicable State authority, and a reference to a ''qualified individual'' is deemed to refer to an individual in the individual market. For purposes of § 155.420(d)(4) of this subchapter ''the Exchange'' is deemed to refer to the Exchange or the health plan, as applicable.

* * * * *

(4) * * *

(ii) In the individual market, subject to § 155.420(c)(5) of this subchapter, individuals must be provided 60 calendar days after the date of an event described in paragraph (b)(2) and (3) of this section to elect coverage, as well as 60 calendar days before certain triggering events as provided for in § 155.420(c)(2) of this subchapter.

* * * * *

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

■ 7. The authority citation for part 150 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

§ 150.103 [Amended]

■ 8. In § 150.103 amend the definition of ''Complaint'' by removing the word ''HIPAA'' and adding in its place ''PHS Act''.

§ 150.205 [Amended]

■ 9. In § 150.205 amend paragraph (e)(2) by removing the word ''HIPAA'' and adding in its place ''PHS Act''.

§ 150.213 [Amended]

■ 10. In § 150.213 amend paragraph (b) by removing the word ''HIPAA'' and adding in its place ''PHS Act''.

§ 150.303 [Amended]

■ 11. In § 150.303 amend paragraph (a) introductory text by removing the word ''HIPAA'' and adding in its place ''PHS Act''.

§ 150.305 [Amended]

■ 12. In § 150.305 amend paragraphs (a)(1), (a)(2), (b)(1), and (c)(1) by removing the word ''HIPAA'' each time it appears and adding in its place ''PHS Act''.

§ 150.311 [Amended]

■ 13. In § 150.311 amend paragraph (g) by removing the word ''HIPAA'' and adding in its place ''PHS Act''.

§ 150.313 [Amended]

■ 14. In § 150.313 amend paragraph (b) by removing the word ''HIPAA'' and adding in its place ''PHS Act''.

■ 15. Amend § 150.401 by revising the definitions of ''Filing date'' and ''Hearing'' to read as follows:

§ 150.401 Definitions.

* * * * *

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

* * * * *

■ 16. Amend § 150.419 by revising paragraph (a) to read as follows:

§ 150.419 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

* * * * *

■ 17. Amend § 150.427 by revising paragraph (a) introductory text and paragraph (b) to read as follows:

§ 150.427 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

* * * * *

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

■ 18. Revise § 150.431 to read as follows:

§ 150.431 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

■ 19. Amend § 150.441 by revising paragraph (e) to read as follows:

§ 150.441 Prehearing conferences.

* * * * *

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

* * * * *

■ 20. Amend § 150.447 by revising paragraph (a) to read as follows:

§ 150.447 The record.

(a) Any testimony that is taken in-person, by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 21. The authority citation for part 153 continues to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 22. Section 153.320 is amended by—
■ a. Revising paragraph (c);
■ b. Redesignating paragraphs (d)(2) through (d)(4) as paragraphs (d)(3) through (d)(5), respectively;
■ c. Adding new paragraph (d)(2);
■ d. Revising newly designated paragraphs (d)(4) and (d)(5)(i); and
■ e. Adding paragraphs (d)(5)(iii) through (v).

The revisions and additions read as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

(c) *Use of methodology for States that do not operate a risk adjustment program.* HHS will specify in notice and comment rulemaking by HHS in advance of the applicable benefit year, the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

(d) * * *

* * * * *

(2) Beginning with the 2023 benefit year, States may request a reduction to otherwise applicable risk adjustment transfers calculated under the HHS-operated risk adjustment methodology for up to 3 years.

(i) A State making a multi-year request must:

(A) Submit evidence and analysis as set forth in paragraphs (d)(1)(i) through (iii) of this section, as applicable, for all years to which the request would apply.

(B) Include with its request a confirmation that it does not anticipate any significant changes to the State market risk pool(s) impacted by its request for the duration for which it is requesting a reduction in risk adjustment transfers.

(C) Respond to HHS requests for supplemental evidence under paragraph (d)(5)(iv) of this section, in the form, manner, and timeframe specified by HHS.

(ii) A State may withdraw its multi-year state reduction request prior to the natural expiration of the request by notifying HHS of its intent to withdraw the request, in the form and manner specified by HHS, 60 calendar days prior to the applicable benefit year's rate setting deadline. The State must also notify its impacted issuers of the withdrawal of its multi-year reduction request at least 45 calendar days prior to the applicable benefit year's rate setting deadline.

* * * * *

(4) *Publication of reduction requests.* HHS will publish State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters and make the supporting evidence available to the public for comment, except to the extent the State requests HHS not publish certain supporting evidence because it contains trade secrets or confidential commercial or financial information as defined in HHS' Freedom of Information regulations under 45 CFR 5.31(d). HHS will publish any approved or denied State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters final rule. Beginning with the 2023 benefit year, all multi-year State reduction requests will be published in the annual HHS notice of benefit and payment parameters that correspond with the first year in which the multi-year flexibility was requested.

(5) * * *

(i) Subject to paragraphs (d)(5)(ii) and (iii) of this section, HHS will approve State reduction requests if HHS determines, based on the review of the information submitted as part of the State's request, along with other relevant factors, including the premium impact of the transfer reduction for the State market risk pool, and other relevant public comments:

* * * * *

(iii) For multi-year requests, HHS may approve a duration that is shorter than what was requested by the State for a multi-year reduction request if HHS determines that the supporting evidence and analysis do not fully support the requested duration.

(iv) HHS may request supplemental evidence from a State with an approved multi-year reduction request at any time after its initial approval, in the form and manner specified by HHS.

(v) HHS retains the ability to terminate or modify a previously approved multi-year reduction request at any time after its initial approval if new additional data or information does not support the continuation of the State's reduction request and the State has not provided sufficient supplemental evidence to rebut such data or information. If the request is terminated or modified by HHS, the State must notify its impacted issuers of the termination or modification of its multi-year reduction request within 15 calendar days of the state's receipt of HHS's notice of termination or modification of its previously approved reduction request.

■ 23. Amend § 153.410 by revising paragraph (d) to read as follows:

§ 153.410 Requests for reinsurance payment.

* * * * *

(d) *Audits and Compliance Reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in § 156.715 of this subchapter.

(1) *Notice of Audit.* HHS will provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented

and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with Audit Activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described in paragraph (d)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (d)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (d)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final Audit Findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to Comply with Audit Activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of reinsurance payments received that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (5)(i) of this section if the reinsurance debt is not paid.

■ 24. Amend § 153.620 by revising paragraph (c) to read as follows:

§ 153.620 Compliance with risk adjustment standards.

* * * * *

(c) *Audits and Compliance Reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with respect to the applicable requirements in this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in § 156.715 of this subchapter.

(1) *Notice of Audit.* HHS will provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with Audit Activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the audit entrance conference described in paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final Audit Findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to Comply with Audit Activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of the risk adjustment (including high-cost risk pool) payments that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any risk adjustment (including high-cost risk pool) payments identified in paragraph (c)(5)(i) of this section.

■ 25. Section 153.630 is amended by—

■ a. Revising paragraphs (d)(2) and (3); and

■ b. Adding paragraphs (g)(4) and (5).

The revisions read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(d) * * *

(2) Within 15 calendar days of the notification by HHS of the findings of a second validation audit (if applicable) or the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the findings of the second validation audit (if applicable) or the calculation of the risk score error rate as a result of risk adjustment data validation, or file a discrepancy report to dispute the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as a result of risk adjustment data validation.

(3) An issuer may appeal the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as result of risk adjustment data validation, under the process set forth in § 156.1220 of this subchapter.

* * * * *

(g) * * *

(4) The issuer only offered small group market carryover coverage during the benefit year that is being audited.

(5) The issuer was the sole issuer in the state market risk pool during the benefit year that is being audited and did not participate in any other market risk pools in the State during the benefit year that is being audited.

■ 26. Section 153.710 is amended—

■ a. By redesignating paragraphs (e) through (g), as paragraphs (f) through (h), respectively; and

■ b. By adding a new paragraph (e); and

■ c. In newly redesignated paragraph (h) introductory text by removing the reference ''paragraph (g)(3)'' and adding in its place the reference ''paragraph (h)(3)''.

The addition reads as follows:

§ 153.710 Data requirements.

* * * * *

(e) *Materiality Threshold.* HHS will consider a discrepancy reported under paragraph (d)(2) of this section to be material if the amount in dispute is equal to or exceeds 1 percent of the applicable payment or charge payable to or due from the issuer for the benefit year, or $100,000, whichever is less.

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 27. 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.

■ 28. Section 155.20 is amended by—

■ a. Adding the definitions of ''Agent or broker direct enrollment technology provider'' and ''Qualified health plan issuer direct enrollment technology provider'';

■ b. Revising the definitions of ''Web-broker''.

The additions and revision read as follows:

§ 155.20 Definitions.

* * * * *

Agent or broker direct enrollment technology provider means a type of web-broker business entity that is not a licensed agent or broker under State law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221.

* * * * *

Qualified health plan issuer direct enrollment technology provider means a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment under §§ 155.221 or 156.1230, including a web-broker that provides services as a direct enrollment technology provider to QHP issuers. A QHP issuer direct enrollment technology provider that provides technology services or provides access to an information technology platform to a QHP issuer will be a downstream or delegated entity of the QHP issuer that participates or applies to participate as a direct enrollment entity.

* * * * *

Web-broker means an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in § 155.220(c)(3) or § 155.221. The term also includes an agent or broker direct enrollment technology provider.

■ 29. Section 155.205 is amended by revising paragraphs (c)(2)(i)(B), (c)(2)(iii)(B), (c)(2)(iv) introductory text, (c)(2)(iv)(B) and (C) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(B) For a web-broker, beginning November 1, 2015, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, this standard also includes telephonic interpreter services in at least 150 languages.

* * * * *

(iii) * * *

(B) For a web-broker, beginning when such entity has been registered with the Exchange for at least 1 year, this standard also includes taglines on website content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. Website content or documents are deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if they are required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. A web-broker that is licensed in and serving multiple States may aggregate the limited English populations in the States it serves to determine the top 15 languages required for taglines. A web-broker may satisfy tagline requirements with respect to website content if it posts a Web link prominently on its home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if it also includes taglines on any critical stand-alone document linked to or embedded in the website.

(iv) For Exchanges, QHP issuers, and web-brokers, website translations.

* * * * *

(B) For a QHP issuer, beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year, or, in cases where a QHP issuer is participating in the enhanced direct enrollment program, twelve (12) months from the date the QHP issuer begins operating its enhanced direct enrollment website in the relevant state for the website content that must be added to its website as a

condition of participation in the FFE enhanced direct enrollment program. If the content of a website maintained by the QHP issuer is critical for obtaining health insurance coverage or access to health care services through a QHP within the meaning of § 156.250 of this subchapter, it must be translated into any non-English language that is spoken by a limited English proficient population that reaches 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

(C) For a web-broker, beginning on the first day of the individual market open enrollment period for the 2017 benefit year, or when such entity has been registered with the Exchange for at least one year, whichever is later, or, in cases where a web-broker is participating in the enhanced direct enrollment program, twelve (12) months from the date the web-broker begins operating its enhanced direct enrollment website in the relevant state for the website content added to its website to participate in the FFE enhanced direct enrollment program, content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees on a website that is maintained by the web-broker must be translated into any non-English language that is spoken by a limited English proficient population that comprises 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary, except that when a web-broker operates in a State using a direct enrollment model under § 155.221(j) of this subpart, the web-broker must translate website content consistent with this paragraph as soon as it begins operations in the State.

* * * * *

■ 30. Section 155.220 is amended by—

■ a. Revising paragraphs (c)(3)(i)(A) and (D);

■ b. Adding paragraph (c)(3)(iii); and

■ c. Adding paragraphs (c)(6) and (n).

The revisions and additions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(A) Disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), except as permitted under paragraph (n) of this section;

* * * * *

(D) Display all QHP data provided by the Exchange, except as permitted under paragraph (n) of this section;

* * * * *

(iii)(A) Notwithstanding paragraph (n)(1) of this section, when permitted under State law, Navigators and certified application counselors may use the website of a web-broker to assist an applicant to enroll in a QHP offered through the Exchange, including to assist an applicant to complete the Exchange eligibility application, if the website displays all QHP data provided by the Exchange related to all QHPs offered through the Exchange consistent with the requirements of § 155.205(b)(1) and (c). Navigators and certified application counselors may use a web-broker website that does not facilitate enrollment in all QHPs offered through the Exchange, so long as the website identifies such QHPs to consumers by prominently displaying a standardized disclaimer provided by the Exchange, and in the manner and form specified by the Exchange, stating that enrollment in such QHPs can be completed through the Exchange website and providing a link to the Exchange website.

(B) A web-broker that makes its website available for use by Navigators and certified application counselors, consistent with the requirements in paragraph (c)(3)(iii)(A) of this section may complete an annual certification process with the Exchange, in the manner and form specified by the Exchange, by attesting to its compliance with the requirements in paragraph (c)(3)(iii)(A) of this section.

* * * * *

(6) In addition to applicable requirements under § 155.221(b)(4), a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's internet website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in the form and manner specified by HHS, of the following:

(i) Operational data including licensure information, points of contact, and third-party relationships;

(ii) Enrollment testing, prior to approval or renewal;

(iii) Website reviews performed by HHS;

(iv) Security and privacy assessment documentation, including:

(A) Penetration testing results;

(B) Security and privacy assessment reports;

(C) Vulnerability scan results;

(D) Plans of action and milestones; and

(E) System security and privacy plans.

(v) Agreements between the web-broker and HHS.

* * * * *

(n) *Exception.* (1) Except in cases where the website of a web-broker is intended to be available for use by Navigators and certified application counselors consistent with paragraph (c)(3)(iii)(A) of this section, if the website of a web-broker does not support enrollment in a QHP offered through an Exchange, the web-broker is not required to provide all of the standardized comparative information required under § 155.205(b)(1) for that QHP, but the web-broker's website must instead:

(i) Prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange website;

(ii) Provide a Web link to the Exchange website; and

(iii) Display the following minimum QHP information consistent with the requirements of § 155.205(c): Issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information.

(2) [Reserved]

■ 31. Section 155.221 is amended—

■ a. By revising paragraphs (b)(1), (3), and (4);

■ b. By redesignating paragraphs (c) through (h) as paragraphs (d) through (i), respectively.

■ c. By adding paragraphs (c) and (j);

■ d. By revising newly redesignated paragraphs (g) introductory text, (g)(6), (g)(7), and (h) by removing the reference to ''paragraph (e)'' and adding in its place a reference to ''paragraph (f)''; and

■ e. By adding paragraph (j).

The additions and revisions read as follows:

§ 155.221 Standards for direct enrollment entities and for third parties to perform audits of direct enrollment entities.

* * * * *

(b) * * *

(1) Display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and any other products, such as excepted benefits, on at least three separate website pages on its non-Exchange website, except as permitted under paragraph (c) of this section;

* * * * *

(3) Limit marketing of non-QHPs during the Exchange eligibility

application and QHP selection process in a manner that minimizes the likelihood that consumers will be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under paragraph (c)(1) of this section;

(4) Demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in the form and manner specified by HHS, of the following:

(i) Business audit documentation including:

(A) Notices of intent to participate including auditor information;

(B) Documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and

(C) Business audit reports including testing results.

(ii) Security and privacy audit documentation including:

(A) Interconnection security agreements;

(B) Security and privacy controls assessment test plans;

(C) Security and privacy assessment reports;

(D) Plans of action and milestones;

(E) Privacy impact assessments;

(F) System security and privacy plans;

(G) Incident response plans; and

(H) Vulnerability scan results.

(iii) Eligibility application audits performed by HHS;

(iv) Online training modules offered by HHS; and

(v) Agreements between the direct enrollment entity and HHS.

* * * * *

(c) *Exceptions to direct enrollment entity display and marketing requirement.* For the Federally-facilitated Exchanges, a direct enrollment entity may:

(1) Display and market QHPs offered through the Exchange and individual health insurance coverage as defined in § 144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated receipt of an offer of an individual coverage health reimbursement arrangement as described in § 146.123(c) of this subchapter, as a standalone benefit, or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage health reimbursement arrangement using a salary reduction arrangement pursuant to a cafeteria plan under section 125 of the Internal Revenue Code, but must clearly distinguish between the QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and prominently communicate that advance payments of the premium tax credit and cost-sharing reductions are available only for QHPs purchased through the Exchange, that advance payments of the premium tax credit are not available to individuals who accept an offer of an individual coverage health reimbursement arrangement or who opt out of an individual coverage health reimbursement arrangement that is considered affordable, and that a salary reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange; and

(2) Display and market Exchange-certified stand-alone dental plans offered outside the Exchange and non-certified stand-alone dental plans on the same website pages.

* * * * *

(j) *Process for States to elect the Exchange Direct Enrollment Option.* Subject to HHS approval, and in addition to or in lieu of the Exchange in the State operating its own consumer-facing eligibility application and enrollment website, a State may elect for the State Exchange, State Exchange on the Federal platform, or Federally-facilitated Exchange in the State to approve one or more enrollment entities described in paragraph (a) of this section to make available a non-Exchange online website to enroll qualified individuals in a QHP offered through the Exchange in the State in a manner that constitutes enrollment through the Exchange, as specified in paragraphs (j)(1) or (2) of this section. Through these approved entities consumers in the State apply for coverage using an eligibility verification and enrollment application as described in § 155.405, and receive eligibility determinations from the Exchange for QHP enrollment, advance payments of the premium tax credit and cost-sharing reductions, as well as receive assessments or determinations from the Exchange for Medicaid and CHIP eligibility in accordance with §§ 155.302 and 155.405.

(1) *Direct Enrollment Option for a State Exchange.* A State may receive approval, under §§ 155.105(b) and 155.106(a), to operate a State Exchange using the direct enrollment option described in paragraph (j) of this section. The State Exchange must meet all federal statutory and regulatory requirements for the operation of an Exchange. An approved State Exchange that wishes to implement this option must submit a revised Exchange Blueprint in accordance with § 155.105(e). In order to obtain approval for the State Exchange to implement this option, the State must:

(i) Demonstrate to HHS operational readiness for the State Exchange and its proposed direct enrollment entities to enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange and to enable individuals to apply for, and receive eligibility determinations for QHP enrollment, advance payments of the premium tax credit and cost-sharing reductions for QHPs from the Exchange, as well as receive assessments or determinations of Medicaid and CHIP eligibility from the Exchange as described in § 155.302, using the eligibility verification and enrollment application described in § 155.405;

(ii) Provide HHS an implementation plan and timeline that details the key activities, milestones, and communication and outreach strategy to support the transition of enrollment operations to direct enrollment entities; and

(iii) Ensure that a minimum of one direct enrollment entity approved by the State meets minimum federal requirements for HHS approval to participate in the Federally-facilitated Exchange direct enrollment program, including requirements at 45 CFR 155.220 and 155.221, and is capable of enrolling all consumers in the State, including those who present complex eligibility scenarios. Where no direct enrollment entity approved by the State meets such minimum federal requirements or possesses the capability to enroll all consumers in the State, the State must offer a consumer-facing website that meets such requirements and possess such capability.

(2) *Direct enrollment option for a State with a Federally-facilitated Exchange or State Exchange on the Federal platform.* Pursuant to a request from a State, the Federally-facilitated Exchange or a State Exchange on the Federal platform may partner with the requesting State to implement the direct enrollment option described in this paragraph (j). The Federally-facilitated Exchange or State-based Exchange on

the Federal platform must meet all federal statutory and regulatory requirements for the operation of an Exchange. In order to obtain approval for the Federally-facilitated Exchange or State Exchange on the Federal platform in a State to implement this option, a State must:

(i) Coordinate with HHS on an implementation plan and timeline that allows for a transition period, developed at the discretion of HHS in consultation with the State, necessary for the Federally-facilitated Exchange to operationalize the necessary changes to implement this option;

(ii) Execute a Federal agreement with HHS that includes the terms and conditions for the arrangement and which defines the division of responsibilities between HHS and the State;

(iii) Agree to procedures developed by HHS for the collection and remittance of the monthly user fee described in § 156.50(c) of this subchapter; and

(iv) Perform and cooperate with activities established by HHS related to oversight and financial integrity requirements in accordance with section 1313 of the Affordable Care Act, including complying with reporting and compliance activities required by HHS and described in the Federal agreement.

■ 32. Section 155.420 is amended by—

■ a. Revising paragraph (a)(4)(ii)(B);

■ b. Adding paragraph (a)(4)(ii)(C);

■ c. Revising paragraph (a)(4)(iii) introductory text;

■ d. Adding paragraphs (b)(5) and (c)(5);

■ e. Revising paragraphs (d)(1)(iii) and (iv);

■ f. Adding paragraph (d)(1)(v);

■ g. Adding paragraph (f).

The revisions and additions read as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(4) * * *

(ii) * * *

(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; or

(C) If an enrollee and his or her dependents become newly ineligible for advance payments of the premium tax credit in accordance with paragraph (d)(6)(i) or (ii) of this section, the Exchange must allow the enrollee and his or her dependents to change to a QHP of a lower metal level, 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), (d)(6)(i) and (ii) of this section for becoming newly eligible or ineligible for CSRs or newly ineligible for APTC, (d)(8), (9), (10) and (12) of this section:

* * * * *

(b) * * *

(5) *Option for earlier effective dates due to untimely notice of triggering event.* At the option of a qualified individual, enrollee or dependent who is eligible to select a plan during a period provided for under paragraph (c)(5) of this section, the Exchange must provide the earliest effective date that would have been available under paragraph (b) of this section, based on the applicable triggering event under paragraph (d) of this section.

(c) * * *

(5) *Availability for individuals who did not receive timely notice of triggering events.* If a qualified individual, enrollee, or dependent did not receive timely notice of an event that triggers eligibility for a special enrollment period under this section, and otherwise was reasonably unaware that a triggering event described in paragraph (d) of this section occurred, the Exchange must allow the qualified individual, enrollee, or when applicable, his or her dependent to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event.

* * * * *

(d) * * *

(1) * * *

(iii) Loses pregnancy-related coverage described under section 1902(a)(10)(A)(i)(IV) and (a)(10)(A)(ii)(IX) of the Act (42 U.S.C. 1396a(a)(10)(A)(i)(IV), (a)(10)(A)(ii)(IX)) or loses access to health care services through coverage provided to a pregnant woman's unborn child, based on the definition of a child in 42 CFR 457.10. The date of the loss of coverage is the last day the qualified individual would have pregnancy-related coverage or access to health care services through the unborn child coverage;

(iv) Loses medically needy coverage as described under section 1902(a)(10)(C) of the Act only once per calendar year. The date of the loss of coverage is the last day the consumer would have medically needy coverage; or

(v) Is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums and the employer completely ceases its contributions to the qualified individual's or dependent's COBRA continuation coverage. The triggering event is the last day of the period for which COBRA continuation coverage is paid for, in whole or in part, by an employer. (See 26 CFR 54.9801–6(a)(3)(ii) for rules regarding termination of employer contributions toward coverage other than COBRA continuation coverage, including coverage under a similar State program.)

* * * * *

(f) *Special enrollment period verification.* Unless a request for modification is granted in accordance with § 155.315(h), an Exchange must conduct verification of applicants' eligibility for special enrollment periods under this section. An Exchange meets this requirement if it verifies eligibility for a number of individuals newly enrolling in Exchange coverage through special enrollment periods that equals at least 75 percent of all special enrollment periods for individuals newly enrolling in Exchange coverage. If the Exchange is unable to verify eligibility for individuals newly enrolling in Exchange coverage through a special enrollment period for which the Exchange requires verification, then the individuals are not eligible for enrollment through the Exchange. In accordance with § 155. 505b(iii), individuals have the right to appeal the eligibility determination.

■ 33. Section 155.726 is amended by revising paragraph (c)(2)(i) to read as follows:

§ 155.726 Enrollment periods under SHOP for plan years beginning on or after January 1, 2018.

* * * * *

(c) * * *

(2) * * *

(i) Experiences an event described in § 155.420(d)(1) (other than paragraphs (d)(1)(ii) and (v)), or experiences an event described in § 155.420(d)(2), (4), (5), (7), (8), (9), (10), (11), or (12);

* * * * *

■ 34. Section 155.1308 is amended by revising paragraph (f)(3)(iv) introductory text to read as follows:

§ 155.1308 Application procedures.

* * * * *

(f) * * *

(3) * * *

(iv) The analyses, actuarial certifications, data, assumptions, analysis, targets and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of the Treasury, as applicable, with the

necessary data to determine that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with guidance published by the Secretary and the Secretary of the Treasury at 83 FR 53575 (Oct. 24, 2018):

* * * * *

■ 35. Section 155.1320 is amended by revising paragraph (a)(1) to read as follows:

§ 155.1320 Monitoring and compliance.

(a) * * * (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of the Treasury, as applicable, a State must comply with all applicable Federal laws, regulations, and interpretive policy statements, as well as guidance published by the Secretary and the Secretary of the Treasury at 83 FR 53575 (Oct. 24, 2018), unless expressly waived. A State must, within the timeframes specified in law, regulation, policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

* * * * *

■ 36. Section 155.1328 is amended by revising paragraph (a) to read as follows:

§ 155.1328 Periodic evaluation requirements.

(a) The Secretary and the Secretary of the Treasury, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with guidance published by the Secretary and the Secretary of the Treasury, including the guidance published at 83 FR 53575 (Oct. 24, 2018), as applicable, and any terms and conditions governing the section 1332 waiver.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 37. 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.

■ 38. Section 156.50 is amended by—

■ a. Revising the heading for paragraph (c);

■ b. Revising paragraph (c)(2);

■ c. Adding paragraph (c)(3);

■ d. Revising the heading for paragraph (d); and

■ e. Revising paragraphs (d)(1) introductory text, (d)(2) introductory text, (d)(2)(i)(A), (B), (d)(2)(ii), (d)(2)(iii)(B), (d)(3) introductory text, (d)(4) through (6), and (d)(7) introductory text;

The revisions and addition read as follows:

§ 156.50 Financial support.

* * * * *

(c) *Requirement for Exchange user fees.* * * *

(2) To support the functions of State-based Exchanges on the Federal platform, unless the State-based Exchange and HHS agree on an alternative mechanism to collect the funds, a participating issuer offering a plan through a State-based Exchange on the Federal Exchange platform for certain Exchange functions described in § 155.200 of this subchapter, as specified in a Federal platform agreement, must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the sum of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for State-Based Exchanges on the Federal platform for the applicable benefit year, multiplied by the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform.

(3) A participating issuer offering a plan through an State-based Exchange on the Federal platform that has adopted the Direct Enrollment option or Federally-facilitated Exchange that has adopted the direct enrollment option as described in § 155.221(j) of this subchapter, as specified in a Federal agreement with HHS, must remit a user fee to HHS each month, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate for the applicable benefit year specified in an annual HHS notice of benefit and payment parameters published in advance of the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform that has adopted the Direct Enrollment option or Federally-facilitated Exchange that has adopted the direct enrollment option.

(d) *Adjustment of Exchange user fees.* (1) A participating issuer offering a plan through a Federally-facilitated Exchange or State-based Exchange on the Federal platform may qualify for an adjustment of the Federally-facilitated Exchange user fee specified in paragraph (c)(1) of this section, the State-based Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, or the user fee specified in paragraph (c)(3) of this section, applicable to issuers participating in a State-based Exchange on the Federal platform or a Federally-facilitated Exchange that has adopted the direct enrollment option under § 155.221(j) of this subchapter, the extent that the participating issuer—

* * * * *

(2) For a participating issuer described in paragraph (d)(1) of this section to receive an adjustment of a user fee under this section—

(i) * * *

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable; and

* * * * *

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the Federally-facilitated Exchange user fee, the State-based Exchange on the Federal platform user fee, or the user fee applicable to issuers participating in a State-based Exchange on the Federal platform or a Federally-facilitated Exchange that has adopted the direct enrollment option § 155.221(j) of this subchapter based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4).

(iii) * * *

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR

54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable;

* * * * *

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, equal in value to the sum of the following:

* * * * *

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1), (2), or (3) of this section, as applicable, in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

(5) Within 60 days of receipt of any adjustment of a user fee under this section, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount that is no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section. No such payment is required with respect to the allowance for administrative costs and margin described in paragraph (d)(3)(ii) of this section. This paragraph does not apply if the participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i) of this section, or is in the same issuer group as the third party administrator.

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1), (2), or (3) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1), (2), or (3) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

* * * * *

■ 39. Section 156.130 is amended by revising paragraph (e) to read as follows:

§ 156.130 Cost-sharing requirements.

* * * * *

(e) *Premium adjustment percentage.* 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. HHS will publish the annual premium adjustment percentage in guidance in January of the calendar year preceding the benefit year for which the premium adjustment percentage is applicable, unless HHS proposes changes to the methodology, in which case, HHS will publish the annual premium adjustment percentage in an annual HHS notice of benefit and payment parameters or another appropriate rulemaking.

* * * * *

■ 40. Section 156.230 is amended by adding paragraph (f) to read as follows:

§ 156.230 Network adequacy standards.

* * * * *

(f) Paragraphs (a) through (e) of this section do not apply to a plan for which an issuer seeks QHP certification or to any certified QHP that does not use a provider network, meaning that the plan or QHP does not condition or differentiate benefits based on whether the issuer has a network participation agreement with the provider that furnishes the covered services.

■ 41. Section 156.295 is amended by—

■ a. Revising the section heading and paragraphs (a) introductory text, (a)(1) and (a)(2) introductory text,

■ b. Removing paragraph (a)(3); and

■ c. Revising paragraph (b) introductory text.

The revisions read as follows:

§ 156.295 Prescription drug distribution and cost reporting by QHP issuers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, a QHP issuer that administers a prescription drug benefit without the use of a pharmacy benefit manager must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

* * * * *

(b) *Limitation on disclosure.* Information disclosed by a QHP issuer under this section shall not be disclosed by HHS, except that HHS may disclose the information in a form which does not disclose the identity of a specific QHP or prices charged for specific drugs, for the following purposes:

* * * * *

■ 42. Section 156.420 is amended by revising paragraphs (a)(1)(i), (a)(2)(i) and (a)(3)(i) to read as follows:

§ 156.420 Plan variations.

(a) * * *

(1) * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * * *

(2) * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * * *

(3) * * *

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

* * * * *

■ 43. Section 156.480 is amended by revising the section heading and paragraph (c) to read as follows:

§ 156.480 Oversight of the administration of the advance payments of the premium tax credit, cost-sharing reductions, and user fee programs.

* * * * *

(c) *Audits and Compliance Reviews.* HHS or its designee may audit or conduct a compliance review of an issuer offering a QHP through an Exchange to assess its compliance with the applicable requirements of this subpart and 45 CFR 156.50. Compliance reviews conducted under this section will follow the standards set forth in § 156.715.

(1) *Notice of Audit.* HHS will provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer under this section.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with Audit Activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described under paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (c)(2)(ii) or (iii), as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (c)(2)(ii) or (iii), as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final Audit Findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 30 calendar days of the issuance of the final audit or compliance review report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to Comply with Audit Activities.* If an issuer fails to comply with the audit activities set forth in this section in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of payments received under this subpart that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (c)(5)(i) of this section if a premium tax credit, cost-sharing reductions, and user fee program debt is not paid.

(6) *Circumstances Requiring HHS Enforcement.* If HHS determines that the State Exchange or State-based Exchange on the Federal platform is not enforcing or fails to substantially enforce the requirements of this subpart or 45 CFR 156.50, then HHS may do so and may pursue the imposition of civil money penalties as specified in § 156.805 for non-compliance by QHP issuers participating in the State Exchange or State Exchange on the Federal platform.

Subpart I—Enforcement Remedies in the Exchanges

■ 44. Subpart I is amended by revising the heading as set forth above.

■ 45. Section 156.800 is amended by revising paragraphs (a) introductory text, and (b) as follows:

§ 156.800 Available remedies; Scope.

(a) *Kinds of sanctions.* HHS may impose the following types of sanctions on QHP issuers in an Exchange that are not in compliance with Exchange standards applicable to issuers offering QHPs in an Exchange:

* * * * *

(b) *Scope.* Sanctions under subpart I are applicable for non-compliance with QHP issuer participation standards and other standards applicable to issuers offering QHPs in a Federally-facilitated Exchange. Sanctions under paragraph (a)(1) of this section are also applicable for non-compliance by QHP issuers participating in State Exchanges and State-based Exchanges on the Federal platform when HHS is responsible for enforcement of the requirements in subpart E of this part and 45 CFR 156.50.

* * * * *

■ 46. Section 156.805 is amended by—

■ a. Revising paragraphs (a) introductory text and (a)(5)(i); and

■ b. Adding paragraph (f) to read.

The revisions and addition read as follows:

§ 156.805 Bases and process for imposing civil money penalties in Exchanges.

(a) *Grounds for imposing civil money penalties.* Civil money penalties may be imposed on an issuer in an Exchange if, based on credible evidence, HHS has reasonably determined that the issuer has engaged in one or more of the following actions:

* * * * *

(5) * * *

(i) To HHS or an Exchange; or

* * * * *

(f) *Circumstances requiring HHS enforcement in State Exchanges and State-based Exchanges on the Federal platform.*

(1) HHS will enforce the requirements of subpart E of this part and 45 CFR 156.50 if a State Exchange or State-based Exchange on the Federal platform notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201 *et seq.* that a State Exchange or State-based Exchange on the Federal platform is failing to substantially enforce these requirements.

(2) If HHS is responsible under paragraph (f)(1) of this section for enforcement of the requirements set forth in subpart E of this part or 45 CFR 156.50, HHS may impose civil money penalties on an issuer in a State Exchange or State-based Exchange on the Federal platform, in accordance with the bases and process for imposing civil money penalties set forth in this section.

Subpart J—Administrative Review of QHP Issuer Sanctions

■ 47. Amend Subpart J by revising the heading to read as set forth above.

■ 48. Section 156.901 is amended by revising the definitions of ''Filing date'' and ''Hearing'' to read as follows.

§ 156.901 Definitions.

* * * * *

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

* * * * *

■ 49. Section 156.903 is amended by revising paragraph (a) as follows:

§ 156.903 Scope of Administrative Law Judge's (ALJ) authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act (5 U.S.C. 554a), to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty of a QHP offered in a Federally-facilitated Exchange, State Exchange, and State-based Exchange on the Federal platform, or the decertification of a QHP offered in a Federally-facilitated Exchange.

* * * * *

■ 50. Section 156.919 is amended by revising paragraph (a) to read as follows:

§ 156.919 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

* * * * *

■ 51. Section 156.927 is amended by revising paragraphs (a) introductory text and (b) to read as follows:

§ 156.927 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

* * * * *

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

■ 52. Section 156.931 is revised to read as follows:

§ 156.931 Acknowledgement of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

■ 53. Section 156.941 is amended by revising paragraph (e) to read as follows:

§ 156.941 Prehearing conferences.

* * * * *

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

* * * * *

■ 54. Section 156.947 is amended by revising paragraph (a) to read as follows:

§ 156.947 The record.

(a) Any testimony that is taken in-person, by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

* * * * *

■ 55. Section 156.1210 is amended by—

■ a. Redesignating paragraph (b) as paragraph (d); and

■ b. Adding new paragraphs (b) and (c).

The additions read as follows:

§ 156.1210 Dispute submission.

* * * * *

(b) *Inaccuracies identified after 90-day period.* With respect to an inaccuracy described under paragraph (a) of this section that is identified and submitted to HHS by the issuer after the end of the 90-day period described in such paragraph, HHS will consider and work with the issuer to resolve the inaccuracy so long as—

(1) The issuer promptly notifies HHS upon identifying the inaccuracy, but in no case later than 15 calendar days after identifying the inaccuracy; and

(2) The failure to identify the inaccuracy and submit it to HHS in a timely manner was not unreasonable or due to the issuer's misconduct or negligence.

(c) *Deadline for describing inaccuracies.* To be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before the later of—

(1) The end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates; or

(2) The date by which HHS notifies issuers that the HHS audit process with respect to the plan year to which such inaccuracy relates has been completed.

(3) If a payment error is discovered after the timeframes set forth in paragraph (c)(1) and (2) of this section, the issuer must notify HHS and repay any overpayments.

* * * * *

■ 56. Section 156.1215 is amended by revising paragraph (b) to read as follows:

§ 156.1215 Payment and collections processes.

* * * * *

(b) Netting of payments and charges for later years. As part of its payment and collections process, HHS may net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of Federally-facilitated Exchange user fees, payment of State-based Exchanges utilizing the Federal platform user fees, and risk adjustment, reinsurance, and risk corridors payments and charges.

* * * * *

■ 57. Section 156.1220 is amended by—

■ a. Revising paragraphs (a)(1)(vii) and (a)(3)(ii);

■ b. Redesignating paragraphs (a)(3)(iii) through (vi) as (a)(3)(iv) through (vii), respectively; and

■ c. Adding new paragraph (a)(3)(iii).

The revision and addition reads as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(1) * * *

(vii) The findings of a second validation audit as a result of risk

adjustment data validation (if applicable) with respect to risk adjustment data for the 2016 benefit year and beyond; or

* * * * *

(3) * * *

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 30 calendar days of the date of the notification under § 153.310(e) of this subchapter;

(iii) For the findings of a second validation audit (if applicable), or the calculation of a risk score error rate as a result of risk adjustment data validation, within 30 calendar days of publication of the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers;

* * * * *

■ 58. Section 156.1240 is amended by adding paragraph (a)(3) to read as follows:

§ 156.1240 Enrollment process for qualified individuals.

(a) * * *

(3) Issuers offering individual market QHPs must accept premium payments for a QHP on behalf of an enrollee that are made from the individual coverage HRA (as described in § 146.123(b) of this subchapter) or qualified small employer health reimbursement arrangement (as described in section 9831(d)(2) of the Internal Revenue Code of 1986, as amended) in which the enrollee is enrolled.

* * * * *

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 59. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 60. Section 158.103 is amended by adding the definition for ''Prescription drug rebates and other price concessions'' in alphabetical order to read as follows:

§ 158.103 Definitions.

* * * * *

Prescription drug rebates and other price concessions means all direct and indirect remuneration received or receivable by an issuer and entities providing pharmacy benefit management services to the issuer, related to the provision of a prescription drug covered by the issuer, regardless from whom the remuneration is received (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, vendor). Direct and indirect remuneration includes discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers, and excluding bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

* * * * *

■ 61. Section 158.240 is amended by adding paragraph (g) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(g) *Rebate prepayment and safe harbor.* An issuer may choose to pay a portion or all of its estimated rebate amount for a given MLR reporting year to enrollees in any form specified in § 158.241 prior to the rebate payment deadlines set forth in §§ 158.240(e) and 158.241(a)(2) and in advance of submitting the MLR report required in § 158.110 to the Secretary. Issuers that choose to prepay a portion or all of their rebates must do so for all eligible enrollees in a given state and market in a non-discriminatory manner. If, after submitting the MLR report required in § 158.110, an issuer determines that its rebate prepayment amount in a given state and market is at least 95 percent, but less than 100 percent, of the total rebate amount owed for the applicable MLR reporting year to enrollees in that state and market, the issuer may, without penalty or late payment interest under paragraph (f) of this section, provide the remaining rebate amount to those enrollees no later than the rebate deadlines in §§ 158.240(e) and 158.241(a)(2) applicable to the following MLR reporting year. If the total rebate owed to an enrollee for the MLR reporting year is above the *de minimis* threshold established in § 158.243(a), the issuer cannot treat the remaining rebate owed to an enrollee after prepayment as *de minimis,* even if the remaining rebate is below the *de minimis* threshold.

■ 62. Section 158.241 is amended by revising paragraph (a)(2) to read as follows:

§ 158.241 Form of rebate.

(a) * * *

(2) For each of the 2011, 2012, and 2013 MLR reporting years, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with the 2014 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after September 30 following the MLR reporting year. If the amount of the rebate exceeds the premium due for October, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with the 2020 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the monthly premium that is due no later than October 30 following the MLR reporting year. If the amount of the rebate exceeds the monthly premium, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited.

* * * * *

■ 63. Subchapter E as added in final rule published on November 27, 2019 (84 FR 65524) and effective on January 1, 2021 is amended by adding part 184 to read as follows:

PART 184—PHARMACY BENEFIT MANAGER STANDARDS UNDER THE AFFORDABLE CARE ACT

Sec.

Authority: 42 U.S.C. 1302, 1320b–23.

§ 184.10 Basis and scope.

(a) *Basis.* (1) This part implements section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title XI of the Social Security Act.

(2) [Reserved]

(b) *Scope.* This part establishes standards for Pharmacy Benefit Managers that administer prescription

drug benefits for health insurance issuers that offer Qualified Health Plans with respect to the offering of such plans.

§ 184.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Health insurance issuer has the meaning given to the term in § 144.103 of this subtitle.

Plan year has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan issuer has the meaning given to the term in § 156.20 of this subchapter.

§ 184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, any entity that provides pharmacy benefits management services on behalf of a qualified health plan (QHP) issuer must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding *bona fide* service fees) that the pharmacy benefits manager (PBM) negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(i) *Bona fide* service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

(ii) [Reserved]

(3) The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(b) *Limitations on disclosure.* Information disclosed by a PBM under this section shall not be disclosed by HHS or by a QHP receiving the information, except that HHS may disclose the information in a form which does not disclose the identity of a specific PBM, QHP, or prices charged for drugs, for the following purposes:

(1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;

(2) To permit the Comptroller General to review the information provided;

(3) To permit the Director of the Congressional Budget Office to review the information provided; or

(4) To States to carry out section 1311 of the Affordable Care Act.

(c) *Penalties.* A PBM that fails to report the information described in paragraph (a) of this section to HHS on a timely basis or knowingly provides false information will be subject to the provisions of section 1927(b)(3)(C) of the Act.

Dated: November 18, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 23, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Dated: November 25, 2020.

David J. Kautter,

Assistant Secretary (Tax Policy), Department of the Treasury.

[FR Doc. 2020–26534 Filed 11–30–20; 5:30 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 85 Friday,

No. 234 December 4, 2020

Part V

Department of Commerce

Bureau of Industry and Security

15 CFR Part 774

Wassenaar Arrangement 2018 Plenary Decisions Implementation; and Other Revisions Related to National Security Controls; Correction; Final Rule

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 201118–0305]

RIN 0694–AH77

Wassenaar Arrangement 2018 Plenary Decisions Implementation; and Other Revisions Related to National Security Controls; Correction

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Correcting amendments.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by making corrections to address errors that were inadvertently introduced with the September 11, 2020, **Federal Register** publication of ''Wassenaar Arrangement 2018 Plenary Decisions Implementation; and Other Revisions Related to National Security Controls (Final Rule)''.

DATES: This rule is effective December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Logan Norton, Regulatory Policy Division, *Logan.Norton@bis.doc.gov,* (202) 812–1762.

SUPPLEMENTARY INFORMATION:

Background

On September 11, 2020, BIS published ''Wassenaar Arrangement 2018 Plenary Decisions Implementation; and Other Revisions Related to National Security Controls (Final Rule)'' (85 FR 56294) in the **Federal Register**. This publication unintentionally introduced errors in Export Control Classification Numbers (ECCNs) 3A001, 3A002, 3A991, 5A002, 7A005, and 9E003, entries located on the Commerce Control List, Supplement No. 1 to part 774 of the EAR. This final rule revises part 774 of the EAR to correct these errors and thereby conform the entries to other recent regulatory changes. These revisions do not change BIS policy, including policy regarding any applicable licensing requirements. The specific revisions set forth in this final rule are detailed below.

3A001 Electronic Items

ECCN 3A001 is corrected as follows:

Adding double quotes around the remaining listed terms that do not have double quotes in the Note following the introductory text of Items paragraph .a. This stylistic convention is consistent with the Wassenaar Arrangement List of Dual-Use Goods and Technologies and the EAR.

Item paragraph a.2 is corrected by replacing ''Electrical Erasable Programmable Read Only Memories (EEPROMS), flash memories, and MRAMs'' with 'non-volatile memories' and by adding a Technical Note to define 'non-volatile memories.'

Item paragraph a.2.c is corrected by adding a plus sign before 125 °C.

The term ''Mega Samples Per Second'' is removed from subparagraphs a.5.a.3, a.5.a.4, and a.5.a.5 in Item paragraph a.5.a, leaving its acronym ''MSPS'' in all three places. Item paragraph a.5.a and the Technical Note below a.5.a are corrected by replacing the term ''output rate'' with the term ''sample rate''. The Technical Notes below Item paragraph a.5.a are corrected by adding an explanation for the resolution of the Analogue-to-Digital Convert (ADC), by removing the explanation for output rate, by replacing single quotes with double quotes around the terms ''interleaved ADCs'' and ''multiple channel ADCs'', and by removing Technical Notes 5 through 9.

Item paragraph a.5.b.2.a (settling time parameter) is corrected by adding ''arrive at or within'' before the reference to 0.024%.

The inclusion Note to 3A001.a.7 is corrected by removing the term ''Simple Programmable Logic Devices (SPLDs)''.

Item paragraph a.14 is corrected by replacing ''Integrated circuits that perform all of the following:'' with ''Integrated circuits that perform or are programmable to perform all of the following:''. Item paragraph a.14 is corrected by replacing the term ''input sample rate'' with the term ''sample rate'', which is defined in part 772. Item paragraph a.14 is also corrected by removing ''Giga Samples Per Second'' from subparagraphs a.14.a.2 and a.14.a.3, leaving the acronym ''GSPS'' in both places. Item paragraph a.14 is also corrected by removing ''Mega Samples Per Second'' from subparagraph a.14.a.5, leaving the acronym ''MSPS''.

Four Technical Notes that further explain the parameters in Item paragraph a. are added below Item paragraph a.14.b.2.

Nota Bene 3 is added after Item paragraph b.4.f to reference 3A001.b.7 for converters and harmonic mixers.

In Item paragraph b.11, double quotes are replaced with single quotes around the term 'frequency synthesizer', the ''or'' is removed from the end of b.11.d, and a Technical Note below Item paragraph b.11.g is added defining 'frequency synthesizer'.

Technical Note 5 after Item paragraph b.12.d is corrected by replacing the reference ''3A001.b.4.12.c'' with ''3A001.b.12.c''.

The parameters for 'primary cells' in Item paragraph e.1.a are corrected by cascading the parameters and by adding a 'continuous power density' parameter and the definition for it in Technical Note 5 below Item paragraph e.1.b. In Item paragraph e.1.b, ''293 K'' and extraneous parentheticals around 20 °C are removed.

Item paragraph 3A001.f, which pertains to rotary input type absolute position encoders, is corrected by removing a single plus/minus sign in front of ''1.0 second of arc''.

Paragraph 3A001.i, which pertains to intensity, amplitude, or phase electro-optic modulators, designed for analog signals (including electro-optic modulators having optical input and output connectors), is added. These items are eligible for License Exception Shipments to Country Group B countries (GBS); therefore, the GBS paragraph under ''List Based License Exceptions'' is accordingly corrected to reference Item paragraph .i. One parameter specified in Item paragraph .i, 'half-wave voltage' ('$V\pi$'), is defined in a Technical Note added below the paragraph.

3A002 General Purpose ''Electronic Assemblies,'' Modules and Equipment

In Item paragraph c.1., the frequency parameter is corrected by replacing ''exceeding 10 MHz'' with ''exceeding 40 MHz'' for signal analyzers having a 3 dB resolution bandwidth (RBW).

Double quotes are replaced with single quotes for the term 'real-time bandwidth' in Item paragraph c.4.a and for the term 'frequency mask trigger' in Item paragraph c.4.b.2. The definitions for these terms are added to the Technical Notes after Item paragraph c.4.b.2. Two additional Technical Notes are added, for a total of four Technical Notes.

Double quotes are added to the term ''sample rate'' in Item paragraph h.1. The words ''an input'' are replaced with the word ''a'' in Item paragraph h.1.

The scientific unit ''billion samples per second'' is replaced with ''Giga Samples Per Second (GSPS)'' in Item paragraph h.1.a.

The scientific unit ''billion samples per second'' is replaced with the acronym ''GSPS'' in Item paragraphs h.1.b and h.1.c.

The scientific unit ''million samples per second'' is replaced with ''Mega Samples Per Second (MSPS)'' in Item paragraph h.1.d.

The scientific unit ''million samples per second'' is replaced with the

acronym ''MSPS'' in Item paragraph h.1.e.

The Technical Note below Item paragraph h.2.c is replaced by four Technical Notes that explain resolution and ''sample rate'' for interleaved and non-interleaved multiple-channel ''electronic assemblies'', modules, or equipment.

3A991 Electronic Devices, and ''Components''

Item paragraph j.2 is corrected by increasing the energy density from 300 to 350 Wh/kg or less.

5A002 ''Information Security'' Systems, Equipment, and ''Components''

Paragraph (4)(a) of Related Controls is corrected by replacing the phrase 'in excess of 56 bits of symmetric key length, or equivalent' with 'described security algorithm'.

Item paragraph .a is corrected by replacing ''usable without ''cryptographic activation'' or has been activated'' with ''useable, has been activated, or can be activated by means of ''cryptographic activation'' not employing a secure mechanism''.

Item paragraph a.4 is corrected by removing ''in excess of''.

Paragraph 2.a of the Technical Notes that follow Item paragraph a.4 is corrected by removing the word ''or'' at the end of the paragraph.

Paragraph 2.b of the Technical Notes that follow Item paragraph a.4 is corrected by replacing ''.'' with ''; or'' at the end.

7A005 ''Satellite Navigation System'' Receiving Equipment

The reference to License Exception Civil End Users, which was removed from the EAR by 85 FR 23470 (April 28, 2020), is deleted from the License Exception section of ECCN 7A005.

9E003 ''Specially Designed'' Assemblies or ''Components'' for Aero Gas Turbine Engines

ECCN 9E003 is corrected as follows:

In Technical Note 2 below Item paragraph a.2 and in the Technical Note below Item paragraph a.5, the single quotes are replaced with double quotes around the term ''steady state mode''. In Technical Note 2 below a.5, the definition for ''steady state mode'', is removed.

Technical Note 4 below the Note to 9E003.c is corrected by replacing ''laser'' with '' ''laser'' beam machining'', replacing ''water jet'' with ''water jet machining'', and by replacing ''Electrical Discharge Machining (EDM) methods'' with ''Electrical Discharge Machining (EDM)''.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. Sections 4801–4852. ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 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, and distributed impacts, and taking into account equity issues). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as a regulatory action that is not significant under section 3(f) of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

2. Notwithstanding any other provision of law, no person may be required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves a collection currently approved by OMB under control number 0694–0088, Simplified Network Application Processing System. This collection includes, among other things, license applications, and carries a burden estimate of 42.5 minutes for a manual or electronic submission for a total burden estimate of 31,878 hours. BIS does not expect the burden hours associated with this collection to change as a result of these correcting amendments.

3. This rule does not contain policies with federalism implications as that term is defined under Executive Order 13132.

Administrative Procedure Act and Regulatory Flexibility Act Requirements

Pursuant to Section 4821 of ECRA, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date. Furthermore, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects in 15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 774 of the Export Administration Regulations (15 CFR parts 730 through 774) is corrected by making the following correcting amendments:

PART 774—[AMENDED]

■ 1. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 2. In Supplement No. 1 to part 774:

■ a. Revise ECCNs 3A001, 3A002, and 3A991 under Category 3, section A;

■ b. Revise ECCN 5A002 under Category 5, Part 2, section A.I.;

■ c. Revise ECCN 7A005 under Category 7, section A; and

■ d. Revise ECCN 9E003 under Category 9, section E.

The revisions read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

Category 3—Electronics

A. ''End Items'', ''Equipment'', ''Accessories'', ''Attachments'', ''Parts'', ''Components'' and ''Systems''

* * * * *

3A001 Electronic items as follows (see List of Items Controlled).

Reason for Control: NS, RS, MT, NP, AT

Control(s)	*Country chart (See Supp. No. 1 to part 738)*
NS applies to "Monolithic Microwave Integrated Circuit" ("MMIC") amplifiers in 3A001.b.2 and discrete microwave transistors in 3A001.b.3, except those 3A001.b.2 and b.3 items being exported or reexported for use in civil telecommunications applications.	NS Column 1
NS applies to entire entry.	NS Column 2
RS applies "Monolithic Microwave Integrated Circuit" ("MMIC") amplifiers in 3A001.b.2 and discrete microwave transistors in 3A001.b.3, except those 3A001.b.2 and b.3 items being exported or reexported for use in civil telecommunications applications.	RS Column 1
MT applies to 3A001.a.1.a when usable in "missiles"; and to 3A001.a.5.a when "designed or modified" for military use, hermetically sealed and rated for operation in the temperature range from below –54 °C to above +125 °C.	MT Column 1
NP applies to pulse discharge capacitors in 3A001.e.2 and superconducting solenoidal electromagnets in 3A001.e.3 that meet or exceed the technical parameters in 3A201.a and 3A201.b, respectively.	NP Column 1
AT applies to entire entry.	AT Column 1

Reporting Requirements: *See § 743.1 of the EAR for reporting requirements for exports under 3A001.b.2 or b.3 under License Exceptions, and Validated End-User authorizations.*

License Requirements Note: *See § 744.17 of the EAR for additional license requirements for microprocessors having a processing speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more, including those incorporating ''information security'' functionality, and associated ''software'' and ''technology'' for the ''production'' or ''development'' of such microprocessors.*

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A for MT or NP; N/A for ''Monolithic Microwave Integrated Circuit'' (''MMIC'') amplifiers in 3A001.b.2 and discrete microwave transistors in 3A001.b.3, except those that are being exported or reexported for use in civil telecommunications applications.

Yes for:

$1500: 3A001.c

$3000: 3A001.b.1, b.2 (exported or reexported for use in civil telecommunications applications), b.3 (exported or reexported for use in civil telecommunications applications), b.9, .d, .e, .f, and .g.

$5000: 3A001.a (except a.1.a and a.5.a when controlled for MT), .b.4 to b.7, and b.12.

GBS: Yes for 3A001.a.1.b, a.2 to a.14 (except .a.5.a when controlled for MT), b.2 (exported or reexported for use in civil telecommunications applications), b.8 (except for ''vacuum electronic devices'' exceeding 18 GHz), b.9., b.10, .g, and .h, and .i.

Special Conditions for STA

STA: License Exception STA may not be used to ship any item in 3A001.b.2 or b.3, except those that are being exported or reexported for use in civil telecommunications applications, to any of the destinations listed in Country Group A:5 or A:6 (See Supplement No.1 to part 740 of the EAR).

List of Items Controlled

Related Controls: (1) See Category XV of the USML for certain ''space-qualified'' electronics and Category XI of the USML for certain ASICs, 'transmit/receive modules,' or 'transmit modules' ''subject to the ITAR'' (see 22 CFR parts 120 through 130). (2) See also 3A101, 3A201, 3A611, 3A991, and 9A515.

Related Definitions: 'Microcircuit' means a device in which a number of passive or active elements are considered as indivisibly associated on or within a continuous structure to perform the function of a circuit. For the purposes of integrated circuits in 3A001.a.1, 5×10^3 Gy (Si) = 5×10^5 Rads (Si); 5×10^6 Gy (Si)/s = 5×10^8 Rads (Si)/s.

Items:

a. General purpose integrated circuits, as follows:

Note 1: *Integrated circuits include the following types:*

— *''Monolithic integrated circuits'';*
— *''Hybrid integrated circuits'';*
— *''Multichip integrated circuits'';*
— *''Film type integrated circuits, including silicon-on-sapphire integrated circuits'';*
— *''Optical integrated circuits'';*
— *''Three dimensional integrated circuits'';*
— *''Monolithic Microwave Integrated Circuits'' (''MMICs'').*

a.1. Integrated circuits designed or rated as radiation hardened to withstand any of the following:

a.1.a. A total dose of 5×10^3 Gy (Si), or higher;

a.1.b. A dose rate upset of 5×10^6 Gy (Si)/s, or higher; *or*

a.1.c. A fluence (integrated flux) of neutrons (1 MeV equivalent) of 5×10^{13} n/cm^2 or higher on silicon, or its equivalent for other materials;

Note: *3A001.a.1.c does not apply to Metal Insulator Semiconductors (MIS).*

a.2. ''Microprocessor microcircuits,'' ''microcomputer microcircuits,'' microcontroller microcircuits, storage integrated circuits manufactured from a compound semiconductor, analog-to-digital converters, integrated circuits that contain analog-to-digital converters and store or process the digitized data, digital-to-analog converters, electro-optical or ''optical integrated circuits'' designed for ''signal processing'', field programmable logic devices, custom integrated circuits for which either the function is unknown or the control status of the equipment in which the integrated circuit will be used in unknown, Fast Fourier Transform (FFT) processors, Static Random-Access Memories (SRAMs), or 'non-volatile memories,' having any of the following:

Technical Note: *'Non-volatile memories' are memories with data retention over a period of time after a power shutdown.*

a.2.a. Rated for operation at an ambient temperature above 398 K (+125 °C);

a.2.b. Rated for operation at an ambient temperature below 218 K (−55 °C); *or*

a.2.c. Rated for operation over the entire ambient temperature range from 218 K (−55 °C) to 398 K (+125 °C);

Note: *3A001.a.2 does not apply to integrated circuits designed for civil automobile or railway train applications.*

a.3. ''Microprocessor microcircuits'', ''microcomputer microcircuits'' and microcontroller microcircuits, manufactured from a compound semiconductor and operating at a clock frequency exceeding 40 MHz;

Note: *3A001.a.3 includes digital signal processors, digital array processors and digital coprocessors.*

a.4. [Reserved]

a.5. Analog-to-Digital Converter (ADC) and Digital-to-Analog Converter (DAC) integrated circuits, as follows:

a.5.a. ADCs having any of the following:

a.5.a.1. A resolution of 8 bit or more, but less than 10 bit, with a ''sample rate'' greater than 1.3 Giga Samples Per Second (GSPS);

a.5.a.2. A resolution of 10 bit or more, but less than 12 bit, with a ''sample rate'' greater than 600 Mega Samples Per Second (MSPS);

a.5.a.3. A resolution of 12 bit or more, but less than 14 bit, with a ''sample rate'' greater than 400 MSPS;

a.5.a.4. A resolution of 14 bit or more, but less than 16 bit, with a ''sample rate'' greater than 250 MSPS; *or*

a.5.a.5. A resolution of 16 bit or more with a ''sample rate'' greater than 65 MSPS;

N.B.: *For integrated circuits that contain analog-to-digital converters and store or process the digitized data see 3A001.a.14.*

Technical Notes:

1. A resolution of n bit corresponds to a quantization of 2^n levels.

2. The resolution of the ADC is the number of bits of the digital output that represents the measured analog input. Effective Number of Bits (ENOB) is not used to determine the resolution of the ADC.

3. For ''multiple channel ADCs'', the ''sample rate'' is not aggregated and the ''sample rate'' is the maximum rate of any single channel.

4. *For ''interleaved ADCs'' or for ''multiple channel ADCs'' that are specified to have an interleaved mode of operation, the ''sample rates'' are aggregated and the ''sample rate'' is the maximum combined total rate of all of the interleaved channels.*

a.5.b. Digital-to-Analog Converters (DAC) having any of the following:

a.5.b.1. A resolution of 10-bit or more but less than 12-bit,with an 'adjusted update rate' of exceeding 3,500 MSPS; *or*

a.5.b.2. A resolution of 12-bit or more and having any of the following:

a.5.b.2.a. An 'adjusted update rate' exceeding 1,250 MSPS but not exceeding 3,500 MSPS, and having any of the following:

a.5.b.2.a.1. A settling time less than 9 ns to arrive at or within 0.024% of full scale from a full scale step; *or*

a.5.b.2.a.2. A 'Spurious Free Dynamic Range' (SFDR) greater than 68 dBc (carrier) when synthesizing a full scale analog signal of 100 MHz or the highest full scale analog signal frequency specified below 100 MHz; *or*

a.5.b.2.b. An 'adjusted update rate' exceeding 3,500 MSPS;

Technical Notes:

1. 'Spurious Free Dynamic Range' (SFDR) is defined as the ratio of the RMS value of the carrier frequency (maximum signal component) at the input of the DAC to the RMS value of the next largest noise or harmonic distortion component at its output.

2. SFDR is determined directly from the specification table or from the characterization plots of SFDR versus frequency.

3. A signal is defined to be full scale when its amplitude is greater than –3 dBfs (full scale).

4. 'Adjusted update rate' for DACs is:

a. For conventional (non-interpolating) DACs, the 'adjusted update rate' is the rate at which the digital signal is converted to an analog signal and the output analog values are changed by the DAC. For DACs where the interpolation mode may be bypassed (interpolation factor of one), the DAC should be considered as a conventional (non-interpolating) DAC.

b. For interpolating DACs (oversampling DACs), the 'adjusted update rate' is defined as the DAC update rate divided by the smallest interpolating factor. For interpolating DACs, the 'adjusted update rate' may be referred to by different terms including:

- *input data rate*
- *input word rate*
- *input sample rate*
- *maximum total input bus rate*
- *maximum DAC clock rate for DAC clock input.*

a.6. Electro-optical and ''optical integrated circuits'', designed for ''signal processing'' and having all of the following:

a.6.a. One or more than one internal ''laser'' diode;

a.6.b. One or more than one internal light detecting element; *and*

a.6.c. Optical waveguides;

a.7. 'Field programmable logic devices' having any of the following:

a.7.a. A maximum number of single-ended digital input/outputs of greater than 700; *or*

a.7.b. An 'aggregate one-way peak serial transceiver data rate' of 500 Gb/s or greater;

Note: *3A001.a.7 includes:*

— *Complex Programmable Logic Devices (CPLDs);*
— *Field Programmable Gate Arrays (FPGAs);*
— *Field Programmable Logic Arrays (FPLAs);*
— *Field Programmable Interconnects (FPICs).*

N.B.: *For integrated circuits having field programmable logic devices that are combined with an analog-to-digital converter, see 3A001.a.14.*

Technical Notes:

1. Maximum number of digital input/outputs in 3A001.a.7.a is also referred to as maximum user input/outputs or maximum available input/outputs, whether the integrated circuit is packaged or bare die.

2. 'Aggregate one-way peak serial transceiver data rate' is the product of the peak serial one-way transceiver data rate times the number of transceivers on the FPGA.

a.8. [Reserved]

a.9. Neural network integrated circuits;

a.10. Custom integrated circuits for which the function is unknown, or the control status of the equipment in which the integrated circuits will be used is unknown to the manufacturer, having any of the following:

a.10.a. More than 1,500 terminals;

a.10.b. A typical ''basic gate propagation delay time'' of less than 0.02 ns; *or*

a.10.c. An operating frequency exceeding 3 GHz;

a.11. Digital integrated circuits, other than those described in 3A001.a.3 to 3A001.a.10 and 3A001.a.12, based upon any compound semiconductor and having any of the following:

a.11.a. An equivalent gate count of more than 3,000 (2 input gates); *or*

a.11.b. A toggle frequency exceeding 1.2 GHz;

a.12. Fast Fourier Transform (FFT) processors having a rated execution time for an N-point complex FFT of less than $(N \log_2 N)/20{,}480$ ms, where N is the number of points;

Technical Note: *When N is equal to 1,024 points, the formula in 3A001.a.12 gives an execution time of 500 μs.*

a.13. Direct Digital Synthesizer (DDS) integrated circuits having any of the following:

a.13.a. A Digital-to-Analog Converter (DAC) clock frequency of 3.5 GHz or more and a DAC resolution of 10 bit or more, but less than 12 bit; *or*

a.13.b. A DAC clock frequency of 1.25 GHz or more and a DAC resolution of 12 bit or more;

Technical Note: *The DAC clock frequency may be specified as the master clock frequency or the input clock frequency.*

a.14. Integrated circuits that perform or are programmable to perform all of the following:

a.14.a. Analog-to-digital conversions meeting any of the following:

a.14.a.1. A resolution of 8 bit or more, but less than 10 bit, with a ''sample rate'' greater than 1.3 Giga Samples Per Second (GSPS);

a.14.a.2. A resolution of 10 bit or more, but less than 12 bit, with a ''sample rate'' greater than 1.0 GSPS;

a.14.a.3. A resolution of 12 bit or more, but less than 14 bit, with a ''sample rate'' greater than 1.0 GSPS;

A.14.a.4. A resolution of 14 bit or more, but less than 16 bit, with a ''sample rate'' greater than 400 Mega Samples Per Second (MSPS); *or*

a.14.a.5. A resolution of 16 bit or more with a ''sample rate'' greater than 180 MSPS; *and*

a.14.b. Any of the following:

a.14.b.1. Storage of digitized data; *or*

a.14.b.2. Processing of digitized data;

N.B. 1: *For analog-to-digital converter integrated circuits see 3A001.a.5.a.*

N.B. 2: *For field programmable logic devices see 3A001.a.7.*

Technical Notes:

1. A resolution of n bit corresponds to a quantization of 2^n levels.

2. The resolution of the ADC is the number of bits of the digital output of the ADC that represents the measured analog input. Effective Number of Bits (ENOB) is not used to determine the resolution of the ADC.

3. For integrated circuits with non-interleaving ''multiple channel ADCs'', the ''sample rate'' is not aggregated and the ''sample rate'' is the maximum rate of any single channel.

4. For integrated circuits with ''interleaved ADCs'' or with ''multiple channel ADCs'' that are specified to have an interleaved mode of operation, the ''sample rates'' are aggregated and the ''sample rate'' is the maximum combined total rate of all of the interleaved channels.

b. Microwave or millimeter wave items, as follows:

Technical Note: *For purposes of 3A001.b, the parameter peak saturated power output may also be referred to on product data sheets as output power, saturated power output, maximum power output, peak power output, or peak envelope power output.*

b.1. ''Vacuum electronic devices'' and cathodes, as follows:

Note 1: *3A001.b.1 does not control ''vacuum electronic devices'' designed or rated for operation in any frequency band and having all of the following:*

a. Does not exceed 31.8 GHz; and

b. Is ''allocated by the ITU'' for radio-communications services, but not for radio-determination.

Note 2: *3A001.b.1 does not control non-''space-qualified'' ''vacuum electronic devices'' having all the following:*

a. An average output power equal to or less than 50 W; and

b. Designed or rated for operation in any frequency band and having all of the following:

1. Exceeds 31.8 GHz but does not exceed 43.5 GHz; and

2. Is ''allocated by the ITU'' for radio-communications services, but not for radio-determination.

b.1.a. Traveling-wave ''vacuum electronic devices,'' pulsed or continuous wave, as follows:

b.1.a.1. Devices operating at frequencies exceeding 31.8 GHz;

b.1.a.2. Devices having a cathode heater with a turn on time to rated RF power of less than 3 seconds;

b.1.a.3. Coupled cavity devices, or derivatives thereof, with a ''fractional bandwidth'' of more than 7% or a peak power exceeding 2.5 kW;

b.1.a.4. Devices based on helix, folded waveguide, or serpentine waveguide circuits, or derivatives thereof, having any of the following:

b.1.a.4.a. An ''instantaneous bandwidth'' of more than one octave, and average power (expressed in kW) times frequency (expressed in GHz) of more than 0.5;

b.1.a.4.b. An ''instantaneous bandwidth'' of one octave or less, and average power (expressed in kW) times frequency (expressed in GHz) of more than 1;

b.1.a.4.c. Being ''space-qualified''; *or*

b.1.a.4.d. Having a gridded electron gun;

b.1.a.5. Devices with a ''fractional bandwidth'' greater than or equal to 10%, with any of the following:

b.1.a.5.a. An annular electron beam;

b.1.a.5.b. A non-axisymmetric electron beam; *or*

b.1.a.5.c. Multiple electron beams;

b.1.b. Crossed-field amplifier ''vacuum electronic devices'' with a gain of more than 17 dB;

b.1.c. Thermionic cathodes, designed for ''vacuum electronic devices,'' producing an emission current density at rated operating conditions exceeding 5 A/cm^2 or a pulsed (non-continuous) current density at rated operating conditions exceeding 10 A/cm^2;

b.1.d. ''Vacuum electronic devices'' with the capability to operate in a 'dual mode.'

Technical Note: *'Dual mode' means the ''vacuum electronic device'' beam current can be intentionally changed between continuous-wave and pulsed mode operation by use of a grid and produces a peak pulse output power greater than the continuous-wave output power.*

b.2. ''Monolithic Microwave Integrated Circuit'' (''MMIC'') amplifiers that are any of the following:

N.B.: *For ''MMIC'' amplifiers that have an integrated phase shifter see 3A001.b.12.*

b.2.a. Rated for operation at frequencies exceeding 2.7 GHz up to and including 6.8 GHz with a ''fractional bandwidth'' greater than 15%, and having any of the following:

b.2.a.1. A peak saturated power output greater than 75 W (48.75 dBm) at any frequency exceeding 2.7 GHz up to and including 2.9 GHz;

b.2.a.2. A peak saturated power output greater than 55 W (47.4 dBm) at any frequency exceeding 2.9 GHz up to and including 3.2 GHz;

b.2.a.3. A peak saturated power output greater than 40 W (46 dBm) at any frequency exceeding 3.2 GHz up to and including 3.7 GHz; *or*

b.2.a.4. A peak saturated power output greater than 20 W (43 dBm) at any frequency exceeding 3.7 GHz up to and including 6.8 GHz;

b.2.b. Rated for operation at frequencies exceeding 6.8 GHz up to and including 16 GHz with a ''fractional bandwidth'' greater than 10%, and having any of the following:

b.2.b.1. A peak saturated power output greater than 10 W (40 dBm) at any frequency exceeding 6.8 GHz up to and including 8.5 GHz; *or*

b.2.b.2. A peak saturated power output greater than 5 W (37 dBm) at any frequency exceeding 8.5 GHz up to and including 16 GHz;

b.2.c. Rated for operation with a peak saturated power output greater than 3 W (34.77 dBm) at any frequency exceeding 16 GHz up to and including 31.8 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.2.d. Rated for operation with a peak saturated power output greater than 0.1 nW (-70 dBm) at any frequency exceeding 31.8 GHz up to and including 37 GHz;

b.2.e. Rated for operation with a peak saturated power output greater than 1 W (30 dBm) at any frequency exceeding 37 GHz up to and including 43.5 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.2.f. Rated for operation with a peak saturated power output greater than 31.62 mW (15 dBm) at any frequency exceeding 43.5 GHz up to and including 75 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.2.g. Rated for operation with a peak saturated power output greater than 10 mW (10 dBm) at any frequency exceeding 75 GHz up to and including 90 GHz, and with a ''fractional bandwidth'' of greater than 5%; *or*

b.2.h. Rated for operation with a peak saturated power output greater than 0.1 nW (-70 dBm) at any frequency exceeding 90 GHz;

Note 1: *[Reserved]*

Note 2: *The control status of the ''MMIC'' whose rated operating frequency includes frequencies listed in more than one frequency range, as defined by 3A001.b.2.a through 3A001.b.2.h, is determined by the lowest peak saturated power output control threshold.*

Note 3: *Notes 1 and 2 following the Category 3 heading for product group A. Systems, Equipment, and Components mean that 3A001.b.2 does not control ''MMICs'' if they are ''specially designed'' for other applications, e.g., telecommunications, radar, automobiles.*

b.3. Discrete microwave transistors that are any of the following:

b.3.a. Rated for operation at frequencies exceeding 2.7 GHz up to and including 6.8 GHz and having any of the following:

b.3.a.1. A peak saturated power output greater than 400 W (56 dBm) at any frequency exceeding 2.7 GHz up to and including 2.9 GHz;

b.3.a.2. A peak saturated power output greater than 205 W (53.12 dBm) at any frequency exceeding 2.9 GHz up to and including 3.2 GHz;

b.3.a.3. A peak saturated power output greater than 115 W (50.61 dBm) at any frequency exceeding 3.2 GHz up to and including 3.7 GHz; *or*

b.3.a.4. A peak saturated power output greater than 60 W (47.78 dBm) at any frequency exceeding 3.7 GHz up to and including 6.8 GHz;

b.3.b. Rated for operation at frequencies exceeding 6.8 GHz up to and including 31.8 GHz and having any of the following:

b.3.b.1. A peak saturated power output greater than 50 W (47 dBm) at any frequency exceeding 6.8 GHz up to and including 8.5 GHz;

b.3.b.2. A peak saturated power output greater than 15 W (41.76 dBm) at any frequency exceeding 8.5 GHz up to and including 12 GHz;

b.3.b.3. A peak saturated power output greater than 40 W (46 dBm) at any frequency exceeding 12 GHz up to and including 16 GHz; *or*

b.3.b.4. A peak saturated power output greater than 7 W (38.45 dBm) at any frequency exceeding 16 GHz up to and including 31.8 GHz;

b.3.c. Rated for operation with a peak saturated power output greater than 0.5 W (27 dBm) at any frequency exceeding 31.8 GHz up to and including 37 GHz;

b.3.d. Rated for operation with a peak saturated power output greater than 1 W (30 dBm) at any frequency exceeding 37 GHz up to and including 43.5 GHz;

b.3.e. Rated for operation with a peak saturated power output greater than 0.1 nW (-70 dBm) at any frequency exceeding 43.5 GHz; *or*

b.3.f. Other than those specified by 3A001.b.3.a to 3A001.b.3.e and rated for operation with a peak saturated power output greater than 5 W (37.0 dBm) at all frequencies exceeding 8.5 GHz up to and including 31.8 GHz;

Note 1: *The control status of a transistor in 3A001.b.3.a through 3A001.b.3.e, whose rated operating frequency includes frequencies listed in more than one frequency range, as defined by 3A001.b.3.a through 3A001.b.3.e, is determined by the lowest peak saturated power output control threshold.*

Note 2: *3A001.b.3 includes bare dice, dice mounted on carriers, or dice mounted in packages. Some discrete transistors may also be referred to as power amplifiers, but the status of these discrete transistors is determined by 3A001.b.3.*

b.4. Microwave solid state amplifiers and microwave assemblies/modules containing microwave solid state amplifiers, that are any of the following:

b.4.a. Rated for operation at frequencies exceeding 2.7 GHz up to and including 6.8 GHz with a ''fractional bandwidth'' greater than 15%, and having any of the following:

b.4.a.1. A peak saturated power output greater than 500 W (57 dBm) at any frequency exceeding 2.7 GHz up to and including 2.9 GHz;

b.4.a.2. A peak saturated power output greater than 270 W (54.3 dBm) at any frequency exceeding 2.9 GHz up to and including 3.2 GHz;

b.4.a.3. A peak saturated power output greater than 200 W (53 dBm) at any frequency exceeding 3.2 GHz up to and including 3.7 GHz; *or*

b.4.a.4. A peak saturated power output greater than 90 W (49.54 dBm) at any frequency exceeding 3.7 GHz up to and including 6.8 GHz;

b.4.b. Rated for operation at frequencies exceeding 6.8 GHz up to and including 31.8 GHz with a ''fractional bandwidth'' greater than 10%, and having any of the following:

b.4.b.1. A peak saturated power output greater than 70 W (48.54 dBm) at any frequency exceeding 6.8 GHz up to and including 8.5 GHz;

b.4.b.2. A peak saturated power output greater than 50 W (47 dBm) at any frequency exceeding 8.5 GHz up to and including 12 GHz;

b.4.b.3. A peak saturated power output greater than 30 W (44.77 dBm) at any frequency exceeding 12 GHz up to and including 16 GHz; *or*

b.4.b.4. A peak saturated power output greater than 20 W (43 dBm) at any frequency exceeding 16 GHz up to and including 31.8 GHz;

b.4.c. Rated for operation with a peak saturated power output greater than 0.5 W (27 dBm) at any frequency exceeding 31.8 GHz up to and including 37 GHz;

b.4.d. Rated for operation with a peak saturated power output greater than 2 W (33 dBm) at any frequency exceeding 37 GHz up to and including 43.5 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.4.e. Rated for operation at frequencies exceeding 43.5 GHz and having any of the following:

b.4.e.1. A peak saturated power output greater than 0.2 W (23 dBm) at any frequency exceeding 43.5 GHz up to and including 75 GHz, and with a ''fractional bandwidth'' of greater than 10%;

b.4.e.2. A peak saturated power output greater than 20 mW (13 dBm) at any frequency exceeding 75 GHz up to and including 90 GHz, and with a ''fractional bandwidth'' of greater than 5%; *or*

b.4.e.3. A peak saturated power output greater than 0.1 nW (-70 dBm) at any frequency exceeding 90 GHz; *or*

b.4.f. [Reserved]

N.B.:

1. *For ''MMIC'' amplifiers see 3A001.b.2.*

2. *For 'transmit/receive modules' and 'transmit modules' see 3A001.b.12.*

3. *For converters and harmonic mixers, designed to extend the operating or frequency range of signal analyzers, signal generators, network analyzers or microwave test receivers, see 3A001.b.7.*

Note 1: *[Reserved]*

Note 2: *The control status of an item whose rated operating frequency includes frequencies listed in more than one frequency range, as defined by 3A001.b.4.a through 3A001.b.4.e, is determined by the lowest peak saturated power output control threshold.*

b.5. Electronically or magnetically tunable band-pass or band-stop filters, having more than 5 tunable resonators capable of tuning across a 1.5:1 frequency band (f_{max}/f_{min}) in less than 10 μs and having any of the following:

b.5.a. A band-pass bandwidth of more than 0.5% of center frequency; *or*

b.5.b. A band-stop bandwidth of less than 0.5% of center frequency;

b.6. [Reserved]

b.7. Converters and harmonic mixers, that are any of the following:

b.7.a. Designed to extend the frequency range of ''signal analyzers'' beyond 90 GHz;

b.7.b. Designed to extend the operating range of signal generators as follows:

b.7.b.1. Beyond 90 GHz;

b.7.b.2. To an output power greater than 100 mW (20 dBm) anywhere within the frequency range exceeding 43.5 GHz but not exceeding 90 GHz;

b.7.c. Designed to extend the operating range of network analyzers as follows:

b.7.c.1. Beyond 110 GHz;

b.7.c.2. To an output power greater than 31.62 mW (15 dBm) anywhere within the frequency range exceeding 43.5 GHz but not exceeding 90 GHz;

b.7.c.3. To an output power greater than 1 mW (0 dBm) anywhere within the frequency range exceeding 90 GHz but not exceeding 110 GHz; *or*

b.7.d. Designed to extend the frequency range of microwave test receivers beyond 110 GHz;

b.8. Microwave power amplifiers containing ''vacuum electronic devices'' controlled by 3A001.b.1 and having all of the following:

b.8.a. Operating frequencies above 3 GHz;

b.8.b. An average output power to mass ratio exceeding 80 W/kg; *and*

b.8.c. A volume of less than 400 cm^3;

Note: *3A001.b.8 does not control equipment designed or rated for operation in any frequency band which is ''allocated by the ITU'' for radio-communications services, but not for radio-determination.*

b.9. Microwave Power Modules (MPM) consisting of, at least, a traveling-wave ''vacuum electronic device,'' a ''Monolithic Microwave Integrated Circuit'' (''MMIC'') and an integrated electronic power conditioner and having all of the following:

b.9.a. A 'turn-on time' from off to fully operational in less than 10 seconds;

b.9.b. A volume less than the maximum rated power in Watts multiplied by 10 cm^3/W; *and*

b.9.c. An ''instantaneous bandwidth'' greater than 1 octave ($f_{max} > 2f_{min}$) and having any of the following:

b.9.c.1. For frequencies equal to or less than 18 GHz, an RF output power greater than 100 W; *or*

b.9.c.2. A frequency greater than 18 GHz;

Technical Notes:

1. To calculate the volume in 3A001.b.9.b, the following example is provided: For a maximum rated power of 20 W, the volume would be: 20 W × 10 cm^3/W = 200 cm^3.

2. The 'turn-on time' in 3A001.b.9.a refers to the time from fully-off to fully operational, i.e., it includes the warm-up time of the MPM.

b.10. Oscillators or oscillator assemblies, specified to operate with a single sideband (SSB) phase noise, in dBc/Hz, less (better) than $-(126 + 20\log_{10}F - 20\log_{10}f)$ anywhere within the range of 10 Hz ≤ F ≤ 10 kHz;

Technical Note: *In 3A001.b.10, F is the offset from the operating frequency in Hz and f is the operating frequency in MHz.*

b.11. 'Frequency synthesizer' ''electronic assemblies'' having a ''frequency switching time'' as specified by any of the following:

b.11.a. Less than 143 ps;

b.11.b. Less than 100 μs for any frequency change exceeding 2.2 GHz within the synthesized frequency range exceeding 4.8 GHz but not exceeding 31.8 GHz;

b.11.c. [Reserved]

b.11.d. Less than 500 μs for any frequency change exceeding 550 MHz within the synthesized frequency range exceeding 31.8 GHz but not exceeding 37 GHz;

b.11.e. Less than 100 μs for any frequency change exceeding 2.2 GHz within the synthesized frequency range exceeding 37 GHz but not exceeding 90 GHz; *or*

b.11.f. [Reserved]

b.11.g. Less than 1 ms within the synthesized frequency range exceeding 90 GHz;

Technical Note: *A 'frequency synthesizer' is any kind of frequency source, regardless of the actual technique used, providing a multiplicity of simultaneous or alternative output frequencies, from one or more outputs, controlled by, derived from or disciplined by a lesser number of standard (or master) frequencies.*

N.B.: *For general purpose ''signal analyzers'', signal generators, network analyzers and microwave test receivers, see 3A002.c, 3A002.d, 3A002.e and 3A002.f, respectively.*

b.12. 'Transmit/receive modules,' 'transmit/receive MMICs,' 'transmit modules,' and 'transmit MMICs,' rated for operation at frequencies above 2.7 GHz and having all of the following:

b.12.a. A peak saturated power output (in watts), P_{sat}, greater than 505.62 divided by the maximum operating frequency (in GHz) squared [$P_{sat} > 505.62\ W*GHz^2/f_{GHz}^2$] for any channel;

b.12.b. A ''fractional bandwidth'' of 5% or greater for any channel;

b.12.c. Any planar side with length d (in cm) equal to or less than 15 divided by the lowest operating frequency in GHz [$d \leq 15cm*GHz*N/f_{GHz}$] where N is the number of transmit or transmit/receive channels; *and*

b.12.d. An electronically variable phase shifter per channel.

Technical Notes:

1. A 'transmit/receive module' is a multifunction ''electronic assembly'' that provides bi-directional amplitude and phase control for transmission and reception of signals.

2. A 'transmit module' is an ''electronic assembly'' that provides amplitude and phase control for transmission of signals.

3. A 'transmit/receive MMIC' is a multifunction ''MMIC'' that provides bi-directional amplitude and phase control for transmission and reception of signals.

4. A 'transmit MMIC' is a ''MMIC'' that provides amplitude and phase control for transmission of signals.

*5. 2.7 GHz should be used as the lowest operating frequency (f_{GHz}) in the formula in 3A001.b.12.c for transmit/receive or transmit modules that have a rated operation range extending downward to 2.7 GHz and below [d≤15cm*GHz*N/2.7 GHz].*

6. 3A001.b.12 applies to 'transmit/receive modules' or 'transmit modules' with or without a heat sink. The value of d in 3A001.b.12.c does not include any portion of the 'transmit/receive module' or 'transmit module' that functions as a heat sink.

7. 'Transmit/receive modules' or 'transmit modules,' 'transmit/receive MMICs' or

'transmit MMICs' may or may not have N integrated radiating antenna elements where N is the number of transmit or transmit/receive channels.

c. Acoustic wave devices as follows and ''specially designed'' ''components'' therefor:

c.1. Surface acoustic wave and surface skimming (shallow bulk) acoustic wave devices, having any of the following:

c.1.a. A carrier frequency exceeding 6 GHz;

c.1.b. A carrier frequency exceeding 1 GHz, but not exceeding 6 GHz and having any of the following:

c.1.b.1. A 'frequency side-lobe rejection' exceeding 65 dB;

c.1.b.2. A product of the maximum delay time and the bandwidth (time in μs and bandwidth in MHz) of more than 100;

c.1.b.3. A bandwidth greater than 250 MHz; *or*

c.1.b.4. A dispersive delay of more than 10 μs; *or*

c.1.c. A carrier frequency of 1 GHz or less and having any of the following:

c.1.c.1. A product of the maximum delay time and the bandwidth (time in μs and bandwidth in MHz) of more than 100;

c.1.c.2. A dispersive delay of more than 10 μs; *or*

c.1.c.3. A 'frequency side-lobe rejection' exceeding 65 dB and a bandwidth greater than 100 MHz;

Technical Note: *'Frequency side-lobe rejection' is the maximum rejection value specified in data sheet.*

c.2. Bulk (volume) acoustic wave devices that permit the direct processing of signals at frequencies exceeding 6 GHz;

c.3. Acoustic-optic ''signal processing'' devices employing interaction between acoustic waves (bulk wave or surface wave) and light waves that permit the direct processing of signals or images, including spectral analysis, correlation or convolution;

Note: *3A001.c does not control acoustic wave devices that are limited to a single band pass, low pass, high pass or notch filtering, or resonating function.*

d. Electronic devices and circuits containing ''components,'' manufactured from ''superconductive'' materials, ''specially designed'' for operation at temperatures below the ''critical temperature'' of at least one of the ''superconductive'' constituents and having any of the following:

d.1. Current switching for digital circuits using ''superconductive'' gates with a product of delay time per gate (in seconds) and power dissipation per gate (in watts) of less than 10^{-14} J; *or*

d.2. Frequency selection at all frequencies using resonant circuits with Q-values exceeding 10,000;

e. High energy devices as follows:

e.1. 'Cells' as follows:

e.1.a 'Primary cells' having any of the following at 20 °C:

e.1.a.1. 'Energy density' exceeding 550 Wh/kg and a 'continuous power density' exceeding 50 W/kg; *or*

e.1.a.2. 'Energy density' exceeding 50 Wh/kg and a 'continuous power density' exceeding 350 W/kg;

e.1.b. 'Secondary cells' having an 'energy density' exceeding 350 Wh/kg at 20 °C;

Technical Notes:

1. For the purpose of 3A001.e.1, 'energy density' (Wh/kg) is calculated from the nominal voltage multiplied by the nominal capacity in ampere-hours (Ah) divided by the mass in kilograms. If the nominal capacity is not stated, energy density is calculated from the nominal voltage squared then multiplied by the discharge duration in hours divided by the discharge load in Ohms and the mass in kilograms.

2. For the purpose of 3A001.e.1, a 'cell' is defined as an electrochemical device, which has positive and negative electrodes, an electrolyte, and is a source of electrical energy. It is the basic building block of a battery.

3. For the purpose of 3A001.e.1.a, a 'primary cell' is a 'cell' that is not designed to be charged by any other source.

4. For the purpose of 3A001.e.1.b, a 'secondary cell' is a 'cell' that is designed to be charged by an external electrical source.

5. For the purpose of 3A001.e.1.a, 'continuous power density' (W/kg) is calculated from the nominal voltage multiplied by the specified maximum continuous discharge current in ampere (A) divided by the mass in kilograms. 'Continuous power density' is also referred to as specific power.

Note: *3A001.e does not control batteries, including single-cell batteries.*

e.2. High energy storage capacitors as follows:

e.2.a. Capacitors with a repetition rate of less than 10 Hz (single shot capacitors) and having all of the following:

e.2.a.1. A voltage rating equal to or more than 5 kV;

e.2.a.2. An energy density equal to or more than 250 J/kg; *and*

e.2.a.3. A total energy equal to or more than 25 kJ;

e.2.b. Capacitors with a repetition rate of 10 Hz or more (repetition rated capacitors) and having all of the following:

e.2.b.1. A voltage rating equal to or more than 5 kV;

e.2.b.2. An energy density equal to or more than 50 J/kg;

e.2.b.3. A total energy equal to or more than 100 J; *and*

e.2.b.4. A charge/discharge cycle life equal to or more than 10,000;

e.3. ''Superconductive'' electromagnets and solenoids, ''specially designed'' to be fully charged or discharged in less than one second and having all of the following:

Note: *3A001.e.3 does not control ''superconductive'' electromagnets or solenoids ''specially designed'' for Magnetic Resonance Imaging (MRI) medical equipment.*

e.3.a. Energy delivered during the discharge exceeding 10 kJ in the first second;

e.3.b. Inner diameter of the current carrying windings of more than 250 mm; *and*

e.3.c. Rated for a magnetic induction of more than 8 T or ''overall current density'' in the winding of more than 300 A/mm^2;

e.4. Solar cells, cell-interconnect-coverglass (CIC) assemblies, solar panels, and solar arrays, which are ''space-qualified,'' having a minimum average efficiency exceeding 20% at an operating temperature of 301 K (28 °C) under simulated 'AM0' illumination with an irradiance of 1,367 Watts per square meter (W/m^2);

Technical Note: *'AM0', or 'Air Mass Zero', refers to the spectral irradiance of sun light in the earth's outer atmosphere when the distance between the earth and sun is one astronomical unit (AU).*

f. Rotary input type absolute position encoders having an ''accuracy'' equal to or less (better) than 1.0 second of arc and ''specially designed'' encoder rings, discs or scales therefor;

g. Solid-state pulsed power switching thyristor devices and 'thyristor modules', using either electrically, optically, or electron radiation controlled switch methods and having any of the following:

g.1. A maximum turn-on current rate of rise (di/dt) greater than 30,000 A/μs and off-state voltage greater than 1,100 V; *or*

g.2. A maximum turn-on current rate of rise (di/dt) greater than 2,000 A/μs and having all of the following:

g.2.a. An off-state peak voltage equal to or greater than 3,000 V; *and*

g.2.b. A peak (surge) current equal to or greater than 3,000 A;

Note 1: *3A001.g. includes:*

—Silicon Controlled Rectifiers (SCRs)
—Electrical Triggering Thyristors (ETTs)
—Light Triggering Thyristors (LTTs)
—Integrated Gate Commutated Thyristors (IGCTs)
—Gate Turn-off Thyristors (GTOs)
—MOS Controlled Thyristors (MCTs)
—Solidtrons

Note 2: *3A001.g does not control thyristor devices and 'thyristor modules' incorporated into equipment designed for civil railway or ''civil aircraft'' applications.*

Technical Note: *For the purposes of 3A001.g, a 'thyristor module' contains one or more thyristor devices.*

h. Solid-state power semiconductor switches, diodes, or 'modules', having all of the following:

h.1. Rated for a maximum operating junction temperature greater than 488 K (215 °C);

h.2. Repetitive peak off-state voltage (blocking voltage) exceeding 300 V; *and*

h.3. Continuous current greater than 1 A.

Technical Note: *For the purposes of 3A001.h, 'modules' contain one or more solid-state power semiconductor switches or diodes.*

Note 1: *Repetitive peak off-state voltage in 3A001.h includes drain to source voltage, collector to emitter voltage, repetitive peak reverse voltage and peak repetitive off-state blocking voltage.*

Note 2: *3A001.h includes:*

—Junction Field Effect Transistors (JFETs)
—Vertical Junction Field Effect Transistors (VJFETs)
—Metal Oxide Semiconductor Field Effect Transistors (MOSFETs)
—Double Diffused Metal Oxide Semiconductor Field Effect Transistor (DMOSFET)
—Insulated Gate Bipolar Transistor (IGBT)
—High Electron Mobility Transistors (HEMTs)
—Bipolar Junction Transistors (BJTs)
—Thyristors and Silicon Controlled Rectifiers (SCRs)

—Gate Turn-Off Thyristors (GTOs)
—Emitter Turn-Off Thyristors (ETOs)
—PiN Diodes
—Schottky Diodes

Note 3: *3A001.h does not apply to switches, diodes, or 'modules', incorporated into equipment designed for civil automobile, civil railway, or ''civil aircraft'' applications.*

i. Intensity, amplitude, or phase electro-optic modulators, designed for analog signals and having any of the following:

i.1. A maximum operating frequency of more than 10 GHz but less than 20 GHz, an optical insertion loss equal to or less than 3 dB and having any of the following:

i.1.a. A 'half-wave voltage' ('Vπ') less than 2.7 V when measured at a frequency of 1 GHz or below; *or*

i.1.b. A 'Vπ' of less than 4 V when measured at a frequency of more than 1 GHz; *or*

i.2. A maximum operating frequency equal to or greater than 20 GHz, an optical insertion loss equal to or less than 3 dB and having any of the following:

i.2.a. A 'Vπ' less than 3.3 V when measured at a frequency of 1 GHz or below; *or*

i.2.b. A 'Vπ' less than 5 V when measured at a frequency of more than 1 GHz.

Note: *3A001.i includes electro-optic modulators having optical input and output connectors (e.g., fiber-optic pigtails).*

Technical Note: *For the purposes of 3A001.i, a 'half-wave voltage' ('Vπ') is the applied voltage necessary to make a phase change of 180 degrees in the wavelength of light propagating through the optical modulator.*

3A002 General purpose ''electronic assemblies,'' modules and equipment, as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, MT, AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to entire entry.	NS Column 2
MT applies to 3A002.h when the parameters in 3A101.a.2.b are met or exceeded.	MT Column 1
AT applies to entire entry.	AT Column 1

Reporting Requirements: *See § 743.1 of the EAR for reporting requirements for exports under License Exceptions, and Validated End-User authorizations.*

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: $3000: 3A002.a, .e, .f, and .g
$5000: 3A002.c to .d, and .h (unless controlled for MT);
GBS: Yes, for 3A002.h (unless controlled for MT)

Special Conditions for STA

STA: License Exception STA may not be used to ship any item in 3A002.g.1 to any of the destinations listed in Country Group A:6 (See Supplement No.1 to part 740 of the EAR).

List of Items Controlled

Related Controls: See Category XV(e)(9) of the USML for certain ''space-qualified'' atomic frequency standards ''subject to the ITAR'' (see 22 CFR parts 120 through 130). See also 3A101, 3A992 and 9A515.x.
Related Definitions: Constant percentage bandwidth filters are also known as octave or fractional octave filters.
Items:

a. Recording equipment and oscilloscopes, as follows:

a.1. to a.5. [Reserved]

N.B.: *For waveform digitizers and transient recorders, see 3A002.h.*

a.6. Digital data recorders having all of the following:

a.6.a. A sustained 'continuous throughput' of more than 6.4 Gbit/s to disk or solid-state drive memory; *and*

a.6.b. ''Signal processing'' of the radio frequency signal data while it is being recorded;

Technical Notes:

1. For recorders with a parallel bus architecture, the 'continuous throughput' rate is the highest word rate multiplied by the number of bits in a word.

2. 'Continuous throughput' is the fastest data rate the instrument can record to disk or solid-state drive memory without the loss of any information while sustaining the input digital data rate or digitizer conversion rate.

a.7. Real-time oscilloscopes having a vertical root-mean-square (rms) noise voltage of less than 2% of full-scale at the vertical scale setting that provides the lowest noise value for any input 3dB bandwidth of 60 GHz or greater per channel;

Note: *3A002.a.7 does not apply to equivalent-time sampling oscilloscopes.*

b. [Reserved]

c. ''Signal analyzers'' as follows:

c.1. ''Signal analyzers'' having a 3 dB resolution bandwidth (RBW) exceeding 40 MHz anywhere within the frequency range exceeding 31.8 GHz but not exceeding 37 GHz;

c.2. ''Signal analyzers'' having Displayed Average Noise Level (DANL) less (better) than −150 dBm/Hz anywhere within the frequency range exceeding 43.5 GHz but not exceeding 90 GHz;

c.3. ''Signal analyzers'' having a frequency exceeding 90 GHz;

c.4. ''Signal analyzers'' having all of the following:

c.4.a. 'Real-time bandwidth' exceeding 170 MHz; *and*

c.4.b. Having any of the following:

c.4.b.1. 100% probability of discovery, with less than a 3 dB reduction from full amplitude due to gaps or windowing effects, of signals having a duration of 15 μs or less; *or*

c.4.b.2. A 'frequency mask trigger' function, with 100% probability of trigger (capture) for signals having a duration of 15 μs or less;

Technical Notes:

1. 'Real-time bandwidth' is the widest frequency range for which the analyzer can continuously transform time-domain data entirely into frequency-domain results, using a Fourier or other discrete time transform that processes every incoming time point, without a reduction of measured amplitude of more than 3 dB below the actual signal amplitude caused by gaps or windowing effects, while outputting or displaying the transformed data.

2. Probability of discovery in 3A002.c.4.b.1 is also referred to as probability of intercept or probability of capture.

3. For the purposes of 3A002.c.4.b.1, the duration for 100% probability of discovery is equivalent to the minimum signal duration necessary for the specified level measurement uncertainty.

4. A 'frequency mask trigger' is a mechanism where the trigger function is able to select a frequency range to be triggered on as a subset of the acquisition bandwidth while ignoring other signals that may also be present within the same acquisition bandwidth. A 'frequency mask trigger' may contain more than one independent set of limits.

Note: *3A002.c.4 does not apply to those ''signal analyzers'' using only constant percentage bandwidth filters (also known as octave or fractional octave filters).*

c.5. [Reserved]

d. Signal generators having any of the following:

d.1. Specified to generate pulse-modulated signals having all of the following, anywhere within the frequency range exceeding 31.8 GHz but not exceeding 37 GHz:

d.1.a. 'Pulse duration' of less than 25 ns; *and*

d.1.b. On/off ratio equal to or exceeding 65 dB;

d.2. An output power exceeding 100 mW (20 dBm) anywhere within the frequency range exceeding 43.5 GHz but not exceeding 90 GHz;

d.3. A ''frequency switching time'' as specified by any of the following:

d.3.a. [Reserved]

d.3.b. Less than 100 μs for any frequency change exceeding 2.2 GHz within the frequency range exceeding 4.8 GHz but not exceeding 31.8 GHz;

d.3.c. [Reserved]

d.3.d. Less than 500 μs for any frequency change exceeding 550 MHz within the frequency range exceeding 31.8 GHz but not exceeding 37 GHz; *or*

d.3.e. Less than 100 μs for any frequency change exceeding 2.2 GHz within the frequency range exceeding 37 GHz but not exceeding 90 GHz;

d.3.f. [Reserved]

d.4. Single sideband (SSB) phase noise, in dBc/Hz, specified as being any of the following:

d.4.a. Less (better) than $-(126 + 20 \log_{10} F - 20\log_{10}f)$ for anywhere within the range of $10 \text{ Hz} \leq F \leq 10 \text{ kHz}$ anywhere within the frequency range exceeding 3.2 GHz but not exceeding 90 GHz; *or*

d.4.b. Less (better) than $-(206 - 20\log_{10}f)$ for anywhere within the range of $10 \text{ kHz} < F \leq 100 \text{ kHz}$ anywhere within the frequency range exceeding 3.2 GHz but not exceeding 90 GHz;

Technical Note: *In 3A002.d.4, F is the offset from the operating frequency in Hz and f is the operating frequency in MHz.*

d.5. An 'RF modulation bandwidth' of digital baseband signals as specified by any of the following:

d.5.a. Exceeding 2.2 GHz within the frequency range exceeding 4.8 GHz but not exceeding 31.8 GHz;

d.5.b. Exceeding 550 MHz within the frequency range exceeding 31.8 GHz but not exceeding 37 GHz; *or*

d.5.c. Exceeding 2.2 GHz within the frequency range exceeding 37 GHz but not exceeding 90 GHz; *or*

Technical Note: *'RF modulation bandwidth' is the Radio Frequency (RF) bandwidth occupied by a digitally encoded baseband signal modulated onto an RF signal. It is also referred to as information bandwidth or vector modulation bandwidth. I/Q digital modulation is the technical method for producing a vector-modulated RF output signal, and that output signal is typically specified as having an 'RF modulation bandwidth'.*

d.6. A maximum frequency exceeding 90 GHz;

Note 1: *For the purpose of 3A002.d, signal generators include arbitrary waveform and function generators.*

Note 2: *3A002.d does not control equipment in which the output frequency is either produced by the addition or subtraction of two or more crystal oscillator frequencies, or by an addition or subtraction followed by a multiplication of the result.*

Technical Notes:

1. The maximum frequency of an arbitrary waveform or function generator is calculated by dividing the sample rate, in samples/second, by a factor of 2.5.

2. For the purposes of 3A002.d.1.a, 'pulse duration' is defined as the time interval from the point on the leading edge that is 50% of the pulse amplitude to the point on the trailing edge that is 50% of the pulse amplitude.

e. Network analyzers having any of the following:

e.1. An output power exceeding 31.62 mW (15 dBm) anywhere within the operating frequency range exceeding 43.5 GHz but not exceeding 90 GHz;

e.2. An output power exceeding 1 mW (0 dBm) anywhere within the operating frequency range exceeding 90 GHz but not exceeding 110 GHz;

e.3. 'Nonlinear vector measurement functionality' at frequencies exceeding 50 GHz but not exceeding 110 GHz; *or*

Technical Note: *'Nonlinear vector measurement functionality' is an instrument's ability to analyze the test results of devices driven into the large-signal domain or the non-linear distortion range.*

e.4. A maximum operating frequency exceeding 110 GHz;

f. Microwave test receivers having all of the following:

f.1. Maximum operating frequency exceeding 110 GHz; *and*

f.2. Being capable of measuring amplitude and phase simultaneously;

g. Atomic frequency standards being any of the following:

g.1. ''Space-qualified'';

g.2. Non-rubidium and having a long-term stability less (better) than 1×10^{-11}/month; *or*

g.3. Non-''space-qualified'' and having all of the following:

g.3.a. Being a rubidium standard;

g.3.b. Long-term stability less (better) than 1×10^{-11}/month; *and*

g.3.c. Total power consumption of less than 1 Watt.

h. ''Electronic assemblies,'' modules or equipment, specified to perform all of the following:

h.1. Analog-to-digital conversions meeting any of the following:

h.1.a. A resolution of 8 bit or more, but less than 10 bit, with a ''sample rate'' greater than 1.3 Giga Samples Per Second (GSPS);

h.1.b. A resolution of 10 bit or more, but less than 12 bit, with a ''sample rate'' greater than 1.0 GSPS;

h.1.c. A resolution of 12 bit or more, but less than 14 bit, with a ''sample rate'' greater than 1.0 GSPS;

h.1.d. A resolution of 14 bit or more but less than 16 bit, with a ''sample rate'' greater than 400 Mega Samples Per Second (MSPS); *or*

h.1.e. A resolution of 16 bit or more with a ''sample rate'' greater than 180 MSPS; *and*

h.2. Any of the following:

h.2.a. Output of digitized data;

h.2.b. Storage of digitized data; *or*

h.2.c. Processing of digitized data;

N.B.: *Digital data recorders, oscilloscopes, ''signal analyzers,'' signal generators, network analyzers and microwave test receivers, are specified by 3A002.a.6, 3A002.a.7, 3A002.c, 3A002.d, 3A002.e and 3A002.f, respectively.*

Technical Notes:

1. A resolution of n bit corresponds to a quantization of 2^n levels.

2. The resolution of the ADC is the number of bits in of the digital output of the ADC that represents the measured analog input word. Effective Number of Bits (ENOB) is not used to determine the resolution of the ADC.

3. For non-interleaved multiple-channel ''electronic assemblies'', modules, or equipment, the ''sample rate'' is not aggregated and the ''sample rate'' is the maximum rate of any single channel.

4. For interleaved channels on multiple-channel ''electronic assemblies'', modules, or equipment, the ''sample rates'' are aggregated and the ''sample rate'' is the maximum combined total rate of all the interleaved channels.

Note: *3A002.h includes ADC cards, waveform digitizers, data acquisition cards, signal acquisition boards and transient recorders.*

* * * * *

3A991 Electronic devices, and ''components'' not controlled by 3A001.

License Requirements

Reason for Control: AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
AT applies to entire entry.	AT Column 1

License Requirements Note: *See § 744.17 of the EAR for additional license requirements for microprocessors having a processing speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more, including those incorporating ''information security'' functionality, and associated ''software'' and ''technology'' for the ''production'' or ''development'' of such microprocessors.*

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A

List of Items Controlled

Related Controls: N/A
Related Definitions: N/A
Items:

a. ''Microprocessor microcircuits'', ''microcomputer microcircuits'', and microcontroller microcircuits having any of the following:

a.1. A performance speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more;

a.2. A clock frequency rate exceeding 25 MHz; *or*

a.3. More than one data or instruction bus or serial communication port that provides a direct external interconnection between parallel ''microprocessor microcircuits'' with a transfer rate of 2.5 Mbyte/s;

b. Storage integrated circuits, as follows:

b.1. Electrical erasable programmable read-only memories (EEPROMs) with a storage capacity;

b.1.a. Exceeding 16 Mbits per package for flash memory types; *or*

b.1.b. Exceeding either of the following limits for all other EEPROM types:

b.1.b.1. Exceeding 1 Mbit per package; *or*

b.1.b.2. Exceeding 256 kbit per package and a maximum access time of less than 80 ns;

b.2. Static random access memories (SRAMs) with a storage capacity:

b.2.a. Exceeding 1 Mbit per package; *or*

b.2.b. Exceeding 256 kbit per package and a maximum access time of less than 25 ns;

c. Analog-to-digital converters having any of the following:

c.1. A resolution of 8 bit or more, but less than 12 bit, with an output rate greater than 200 million words per second;

c.2. A resolution of 12 bit with an output rate greater than 105 million words per second;

c.3. A resolution of more than 12 bit but equal to or less than 14 bit with an output rate greater than 10 million words per second; *or*

c.4. A resolution of more than 14 bit with an output rate greater than 2.5 million words per second;

d. Field programmable logic devices having a maximum number of single-ended digital input/outputs between 200 and 700;

e. Fast Fourier Transform (FFT) processors having a rated execution time for a 1,024 point complex FFT of less than 1 ms;

f. Custom integrated circuits for which either the function is unknown, or the control status of the equipment in which the integrated circuits will be used is unknown to the manufacturer, having any of the following:

f.1. More than 144 terminals; *or*

f.2. A typical ''basic propagation delay time'' of less than 0.4 ns;

g. Traveling-wave ''vacuum electronic devices,'' pulsed or continuous wave, as follows:

g.1. Coupled cavity devices, or derivatives thereof;

g.2. Helix devices based on helix, folded waveguide, or serpentine waveguide circuits, *or* derivatives thereof, with any of the following:

g.2.a. An ''instantaneous bandwidth'' of half an octave or more; *and*

g.2.b. The product of the rated average output power (expressed in kW) and the maximum operating frequency (expressed in GHz) of more than 0.2;

g.2.c. An ''instantaneous bandwidth'' of less than half an octave; *and*

g.2.d. The product of the rated average output power (expressed in kW) and the maximum operating frequency (expressed in GHz) of more than 0.4;

h. Flexible waveguides designed for use at frequencies exceeding 40 GHz;

i. Surface acoustic wave and surface skimming (shallow bulk) acoustic wave devices (*i.e.,* ''signal processing'' devices employing elastic waves in materials), having either of the following:

i.1. A carrier frequency exceeding 1 GHz; *or*

i.2. A carrier frequency of 1 GHz or less; *and*

i.2.a. A frequency side-lobe rejection exceeding 55 Db;

i.2.b. A product of the maximum delay time and bandwidth (time in microseconds and bandwidth in MHz) of more than 100; *or*

i.2.c. A dispersive delay of more than 10 microseconds;

j. Cells as follows:

j.1. Primary cells having an energy density of 550 Wh/kg or less at 293 K (20 °C);

j.2. Secondary cells having an energy density of 350 Wh/kg or less at 293 K (20 °C);

Note: *3A991.j does not control batteries, including single cell batteries.*

Technical Notes:

1. For the purpose of 3A991.j energy density (Wh/kg) is calculated from the nominal voltage multiplied by the nominal capacity in ampere-hours divided by the mass in kilograms. If the nominal capacity is not stated, energy density is calculated from the nominal voltage squared then multiplied by the discharge duration in hours divided by the discharge load in Ohms and the mass in kilograms.

2. For the purpose of 3A991.j, a 'cell' is defined as an electrochemical device, which has positive and negative electrodes, and electrolyte, and is a source of electrical energy. It is the basic building block of a battery.

3. For the purpose of 3A991.j.1, a 'primary cell' is a 'cell' that is not designed to be charged by any other source.

4. For the purpose of 3A991.j.2, a 'secondary cell' is a 'cell' that is designed to be charged by an external electrical source.

k. ''Superconductive'' electromagnets or solenoids ''specially designed'' to be fully charged or discharged in less than one minute, having all of the following:

Note: *3A991.k does not control ''superconductive'' electromagnets or solenoids designed for Magnetic Resonance Imaging (MRI) medical equipment.*

k.1. Maximum energy delivered during the discharge divided by the duration of the discharge of more than 500 kJ per minute;

k.2. Inner diameter of the current carrying windings of more than 250 mm; *and*

k.3. Rated for a magnetic induction of more than 8T or ''overall current density'' in the winding of more than 300 A/mm^2;

l. Circuits or systems for electromagnetic energy storage, containing ''components'' manufactured from ''superconductive'' materials ''specially designed'' for operation at temperatures below the ''critical temperature'' of at least one of their ''superconductive'' constituents, having all of the following:

l.1. Resonant operating frequencies exceeding 1 MHz;

l.2. A stored energy density of 1 MJ/M^3 or more; *and*

l.3. A discharge time of less than 1 ms;

m. Hydrogen/hydrogen-isotope thyratrons of ceramic-metal construction and rate for a peak current of 500 A or more;

n. Digital integrated circuits based on any compound semiconductor having an equivalent gate count of more than 300 (2 input gates);

o. Solar cells, cell-interconnect-coverglass (CIC) assemblies, solar panels, and solar arrays, which are ''space qualified'' and not controlled by 3A001.e.4.

* * * * *

Category 5—Telecommunications and ''Information Security''

* * * * *

Part 2—''Information Security''

* * * * *

A. ''End Items'', ''Equipment'', ''Accessories'', ''Attachments'', ''Parts'', ''Components'' and ''Systems''

I. Cryptographic ''Information Security''

5A002 ''Information security'' systems, equipment and ''components,'' as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, AT, EI

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to entire entry.	NS Column 1
AT applies to entire entry.	AT Column 1
EI applies to entire entry.	Refer to § 742.15 of the EAR

License Requirements Note: *See § 744.17 of the EAR for additional license requirements for microprocessors having a processing speed of 5 GFLOPS or more and an arithmetic logic unit with an access width of 32 bit or more, including those incorporating ''information security'' functionality, and associated ''software'' and ''technology'' for the ''production'' or ''development'' of such microprocessors.*

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: Yes: $500 for ''components''.

N/A for systems and equipment.

GBS: N/A

ENC: Yes for certain EI controlled commodities, see § 740.17 of the EAR for eligibility.

List of Items Controlled

Related Controls: (1) ECCN 5A002.a controls ''component'' providing the means or functions necessary for ''information security.'' All such ''components'' are presumptively ''specially designed'' and controlled by 5A002.a. (2) See USML Categories XI (including XI(b)) and XIII(b) (including XIII(b)(2)) for controls on systems, equipment, and components described in 5A002.d or .e that are subject to the ITAR. (3) For ''satellite navigation system'' receiving equipment containing or employing decryption see 7A005, and for related decryption ''software'' and ''technology'' see 7D005 and 7E001. (4) Noting that items may be controlled elsewhere on the CCL, examples of items not controlled by ECCN 5A002.a.4 include the following: (a) An automobile where the only 'cryptography for data confidentiality' having a 'described security algorithm' is performed by a Category 5—Part 2 Note 3 eligible mobile telephone that is built into the car. In this case, secure phone communications support a non-primary function of the automobile but the mobile telephone (equipment), as a standalone item, is not controlled by ECCN 5A002 because it is excluded by the Cryptography Note (Note 3) (See ECCN 5A992.c). (b) An exercise bike with an embedded Category 5—Part 2 Note 3 eligible web browser, where the only controlled cryptography is performed by the web browser. In this case, secure web browsing supports a non-primary function of the exercise bike but the web browser (''software''), as a standalone item, is not controlled by ECCN 5D002 because it is excluded by the Cryptography Note (Note 3) (See ECCN 5D992.c). (5) After classification or self-classification in accordance with § 740.17(b) of the EAR, mass market encryption commodities that meet eligibility requirements are released from ''EI'' and ''NS'' controls. These commodities are designated 5A992.c.

Related Definitions: N/A

Items:

a. Designed or modified to use 'cryptography for data confidentiality' having a 'described security algorithm', where that cryptographic capability is useable, has been activated, or can be activated by means of ''cryptographic activation'' not employing a secure mechanism, as follows:

a.1. Items having ''information security'' as a primary function;

a.2. Digital communication or networking systems, equipment or components, not specified in paragraph 5A002.a.1;

a.3. Computers, other items having information storage or processing as a primary function, and components therefor, not specified in paragraphs 5A002.a.1 or .a.2;

N.B.: *For operating systems see also 5D002.a.1 and .c.1.*

a.4. Items, not specified in paragraphs 5A002.a.1 to a.3, where the 'cryptography for

data confidentiality' having a 'described security algorithm' meets all of the following:

a.4.a. It supports a non-primary function of the item; *and*

a.4.b. It is performed by incorporated equipment or ''software'' that would, as a standalone item, be specified by ECCNs 5A002, 5A003, 5A004, 5B002 or 5D002.

N.B. to paragraph a.4: *See Related Control Paragraph (4) of this ECCN 5A002 for examples of items not controlled by 5A002.a.4.*

Technical Notes:

1. For the purposes of 5A002.a, 'cryptography for data confidentiality' means ''cryptography'' that employs digital techniques and performs any cryptographic function other than any of the following:

1.a. ''Authentication;''

1.b. Digital signature;

1.c. Data integrity;

1.d. Non-repudiation;

1.e. Digital rights management, including the execution of copy-protected ''software;''

1.f. Encryption or decryption in support of entertainment, mass commercial broadcasts or medical records management; or

1.g. Key management in support of any function described in paragraphs 1.a to 1.f of this Technical Note paragraph 1.

2. For the purposes of 5A002.a, 'described security algorithm' means any of the following:

2.a. A ''symmetric algorithm'' employing a key length in excess of 56 bits, not including parity bits;

2.b. An ''asymmetric algorithm'' where the security of the algorithm is based on any of the following:

2.b.1. Factorization of integers in excess of 512 bits (e.g., RSA);

2.b.2. Computation of discrete logarithms in a multiplicative group of a finite field of size greater than 512 bits (e.g., Diffie-Hellman over Z/pZ); or

2.b.3. Discrete logarithms in a group other than mentioned in paragraph 2.b.2 of this Technical Note in excess of 112 bits (e.g., Diffie-Hellman over an elliptic curve); or

2.c. An ''asymmetric algorithm'' where the security of the algorithm is based on any of the following:

2.c.1. Shortest vector or closest vector problems associated with lattices (e.g., NewHope, Frodo, NTRUEncrypt, Kyber, Titanium);

2.c.2. Finding isogenies between Supersingular elliptic curves (e.g., Supersingular Isogeny Key Encapsulation); or

2.c.3. Decoding random codes (e.g., McEliece, Niederreiter).

Technical Note: *An algorithm described by Technical Note 2.c. may be referred to as being post-quantum, quantum-safe or quantum-resistant.*

Note 1: *Details of items must be accessible and provided upon request, in order to establish any of the following:*

a. Whether the item meets the criteria of 5A002.a.1 to a.4; or

b. Whether the cryptographic capability for data confidentiality specified by 5A002.a is usable without ''cryptographic activation.''

Note 2: *5A002.a does not control any of the following items, or specially designed ''information security'' components therefor:*

a. Smart cards and smart card 'readers/writers' as follows:

a.1. A smart card or an electronically readable personal document (e.g., token coin, e-passport) that meets any of the following:

a.1.a. The cryptographic capability meets all of the following:

a.1.a.1. It is restricted for use in any of the following:

a.1.a.1.a. Equipment or systems, not described by 5A002.a.1 to a.4;

a.1.a.1.b. Equipment or systems, not using 'cryptography for data confidentiality' having a 'described security algorithm'; or

a.1.a.1.c. Equipment or systems, excluded from 5A002.a by entries b. to f. of this Note; and

a.1.a.2. It cannot be reprogrammed for any other use; or

a.1.b. Having all of the following:

a.1.b.1. It is specially designed and limited to allow protection of 'personal data' stored within;

a.1.b.2. Has been, or can only be, personalized for public or commercial transactions or individual identification; and

a.1.b.3. Where the cryptographic capability is not user-accessible;

Technical Note to paragraph a.1.b of Note 2: *'Personal data' includes any data specific to a particular person or entity, such as the amount of money stored and data necessary for ''authentication.''*

a.2. 'Readers/writers' specially designed or modified, and limited, for items specified by paragraph a.1 of this Note;

Technical Note to paragraph a.2 of Note 2: *'Readers/writers' include equipment that communicates with smart cards or electronically readable documents through a network.*

b. Cryptographic equipment specially designed and limited for banking use or 'money transactions';

Technical Note to paragraph b. of Note 2: *'Money transactions' in 5A002 Note 2 paragraph b. includes the collection and settlement of fares or credit functions.*

c. *Portable or mobile radiotelephones for civil use (e.g., for use with commercial civil cellular radio communication systems) that are not capable of transmitting encrypted data directly to another radiotelephone or equipment (other than Radio Access Network (RAN) equipment), nor of passing encrypted data through RAN equipment (e.g., Radio Network Controller (RNC) or Base Station Controller (BSC));*

d. Cordless telephone equipment not capable of end-to-end encryption where the maximum effective range of unboosted cordless operation (i.e., a single, unrelayed hop between terminal and home base station) is less than 400 meters according to the manufacturer's specifications;

e. Portable or mobile radiotelephones and similar client wireless devices for civil use, that implement only published or commercial cryptographic standards (except for anti-piracy functions, which may be non-published) and also meet the provisions of paragraphs a.2 to a.4 of the Cryptography Note (Note 3 in Category 5—Part 2), that have been customized for a specific civil industry application with features that do not affect the cryptographic functionality of these original non-customized devices;

f. Items, where the ''information security'' functionality is limited to wireless ''personal area network'' functionality, meeting all of the following:

f.1. Implement only published or commercial cryptographic standards; and

f.2. The cryptographic capability is limited to a nominal operating range not exceeding 30 meters according to the manufacturer's specifications, or not exceeding 100 meters according to the manufacturer's specifications for equipment that cannot interconnect with more than seven devices;

g. Mobile telecommunications Radio Access Network (RAN) equipment designed for civil use, which also meet the provisions of paragraphs a.2 to a.4 of the Cryptography Note (Note 3 in Category 5—Part 2), having an RF output power limited to 0.1W (20 dBm) or less, and supporting 16 or fewer concurrent users;

h. Routers, switches or relays, where the ''information security'' functionality is limited to the tasks of ''Operations, Administration or Maintenance'' (''OAM'') implementing only published or commercial cryptographic standards;

i. General purpose computing equipment or servers, where the ''information security'' functionality meets all of the following:

i.1. Uses only published or commercial cryptographic standards; and

i.2. Is any of the following:

i.2.a. Integral to a CPU that meets the provisions of Note 3 in Category 5—Part 2;

i.2.b. Integral to an operating system that is not specified by 5D002; or

i.2.c. Limited to ''OAM'' of the equipment; or

j. Items specially designed for a 'connected civil industry application', meeting all of the following:

j.1. Being any of the following:

j.1.a. A network-capable endpoint device meeting any of the following:

j.1.a.1. The ''information security'' functionality is limited to securing 'non-arbitrary data' or the tasks of ''Operations, Administration or Maintenance'' (''OAM''); or

j.1.a.2. The device is limited to a specific 'connected civil industry application'; or

j.1.b. Networking equipment meeting all of the following:

j.1.b.1. Being specially designed to communicate with the devices specified by paragraph j.1.a above; and

j.1.b.2. The ''information security'' functionality is limited to supporting the 'connected civil industry application' of devices specified by paragraph j.1.a above, or the tasks of ''OAM'' of this networking equipment or of other items specified by paragraph j. of this Note; and

j.2. Where the ''information security'' functionality implements only published or commercial cryptographic standards, and the cryptographic functionality cannot easily be changed by the user.

Technical Notes:

1. 'Connected civil industry application' means a network-connected consumer or civil industry application other than ''information security'', digital communication, general purpose networking or computing.

2. 'Non-arbitrary data' means sensor or metering data directly related to the stability, performance or physical measurement of a system (e.g., temperature, pressure, flow rate, mass, volume, voltage, physical location, etc.), that cannot be changed by the user of the device.

b. Being a 'cryptographic activation token';

Technical Note: *A 'cryptographic activation token' is an item designed or modified for any of the following:*

1. Converting, by means of ''cryptographic activation'', an item not specified by Category 5—Part 2 into an item specified by 5A002.a or 5D002.c.1, and not released by the Cryptography Note (Note 3 in Category 5—Part 2); or

2. Enabling, by means of ''cryptographic activation'', additional functionality specified by 5A002.a of an item already specified by Category 5—Part 2;

c. Designed or modified to use or perform ''quantum cryptography;''

Technical Note: *''Quantum cryptography'' is also known as Quantum Key Distribution (QKD).*

d. Designed or modified to use cryptographic techniques to generate channelizing codes, scrambling codes or network identification codes, for systems using ultra-wideband modulation techniques and having any of the following:

d.1. A bandwidth exceeding 500 MHz; *or*

d.2. A ''fractional bandwidth'' of 20% or more;

e. Designed or modified to use cryptographic techniques to generate the spreading code for ''spread spectrum'' systems, not specified by 5A002.d, including the hopping code for ''frequency hopping'' systems.

* * * * *

Category 7—Navigation and Avionics

A. ''End Items'', ''Equipment'', ''Accessories'', ''Attachments'', ''Parts'', ''Components'' and ''Systems''

* * * * *

7A005 ''Satellite navigation system'' receiving equipment having any of the following and ''specially designed'' ''components'' therefor.

License Requirements

Reason for Control: NS, MT and AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to 7A005.b.	NS Column 1
MT applies to commodities in 7A005.b that meet or exceed the parameters of 7A105.	MT Column 1
AT applies to 7A005.b.	AT Column 1

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) See also ECCNs 7A105, 7A611 and 7A994. Commercially available ''satellite navigation system'' receivers do not typically employ decryption or adaptive antennae and are classified as 7A994. (2) See USML Category XII(d) for ''satellite navigation system'' receiving equipment subject to the ITAR and USML Category XI(c)(10) for antennae that are subject to the ITAR. (3) Items that otherwise would be covered by ECCN 7A005.a are ''subject to the ITAR'' (see 22 CFR parts 120 through 130).

Related Definitions: N/A

Items:

a. Employing a decryption algorithm ''specially designed'' or modified for government use to access the ranging code for position and time; *or*

b. Employing 'adaptive antenna systems'.

Note: *7A005.b does not apply to ''satellite navigation system'' receiving equipment that only uses ''components'' designed to filter, switch, or combine signals from multiple omni-directional antennas that do not implement adaptive antenna techniques.*

Technical Note: *For the purposes of 7A005.b 'adaptive antenna systems' dynamically generate one or more spatial nulls in an antenna array pattern by signal processing in the time domain or frequency domain.*

* * * * *

Category 9—Aerospace and Propulsion

* * * * *

E. ''Technology''

* * * * *

9E003 Other ''technology'' as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, SI, AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to entire entry.	NS Column 1
SI applies to 9E003.a.1 through a.8, .h, .i, and .k.	See § 742.14 of the EAR for additional information
AT applies to entire entry.	AT Column 1

Reporting Requirements

See § 743.1 of the EAR for reporting requirements for exports under License Exceptions, and Validated End-User authorizations.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit any technology in 9E003.a.1, 9E003.a.2 to a.5, 9E003.a.8, or 9E003.h to any of the destinations listed in Country Group A:6 (See Supplement No.1 to part 740 of the EAR).

List of Items Controlled

Related Controls: (1) Hot section ''technology'' specifically designed, modified, or equipped for military uses or purposes, or developed principally with U.S. Department of Defense funding, is ''subject to the ITAR'' (see 22 CFR parts 120 through 130). (2) ''Technology'' is subject to the EAR when actually applied to a commercial ''aircraft'' engine program. Exporters may seek to establish commercial application either on a case-by-case basis through submission of documentation demonstrating application to a commercial program in requesting an export license from the Department Commerce in respect to a specific export, or in the case of use for broad categories of ''aircraft,'' engines, ''parts'' or ''components,'' a commodity jurisdiction determination from the Department of State.

Related Definitions: N/A

Items:

a. ''Technology'' ''required'' for the ''development'' or ''production'' of any of the following gas turbine engine ''parts,'' ''components'' or systems:

a.1. Gas turbine blades, vanes or ''tip shrouds'', made from Directionally Solidified (DS) or Single Crystal (SC) alloys and having (in the 001 Miller Index Direction) a stress-rupture life exceeding 400 hours at 1,273 K (1,000 °C) at a stress of 200 MPa, based on the average property values;

Technical Note: *For the purposes of 9E003.a.1, stress-rupture life testing is typically conducted on a test specimen.*

a.2. Combustors having any of the following:

a.2.a. 'Thermally decoupled liners' designed to operate at 'combustor exit temperature' exceeding 1,883 K (1,610 °C);

a.2.b. Non-metallic liners;

a.2.c. Non-metallic shells; *or*

a.2.d. Liners designed to operate at 'combustor exit temperature' exceeding 1,883 K (1,610 °C) and having holes that meet the parameters specified by 9E003.c;

Note: *The ''required'' ''technology'' for holes in 9E003.a.2 is limited to the derivation of the geometry and location of the holes.*

Technical Notes:

1. 'Thermally decoupled liners' are liners that feature at least a support structure designed to carry mechanical loads and a combustion facing structure designed to protect the support structure from the heat of combustion. The combustion facing structure and support structure have independent thermal displacement (mechanical displacement due to thermal load) with respect to one another, i.e., they are thermally decoupled.

2. 'Combustor exit temperature' is the bulk average gas path total (stagnation) temperature between the combustor exit plane and the leading edge of the turbine inlet guide vane (i.e., measured at engine station T40 as defined in SAE ARP 755A) when the engine is running in a ''steady state mode'' of operation at the certificated maximum continuous operating temperature.

N.B.: *See 9E003.c for ''technology'' ''required'' for manufacturing cooling holes.*

a.3. ''Parts'' or ''components,'' that are any of the following:

a.3.a. Manufactured from organic ''composite'' materials designed to operate above 588 K (315 °C);

a.3.b. Manufactured from any of the following:

a.3.b.1. Metal ''matrix'' ''composites'' reinforced by any of the following:

a.3.b.1.a. Materials controlled by 1C007;

a.3.b.1.b. ''Fibrous or filamentary materials'' specified by 1C010; *or*

a.3.b.1.c. Aluminides specified by 1C002.a; *or*

a.3.b.2. Ceramic ''matrix'' ''composites'' specified by 1C007; *or*

a.3.c. Stators, vanes, blades, tip seals (shrouds), rotating blings, rotating blisks or 'splitter ducts', that are all of the following:

a.3.c.1. Not specified in 9E003.a.3.a;

a.3.c.2. Designed for compressors or fans; *and*

a.3.c.3. Manufactured from material controlled by 1C010.e with resins controlled by 1C008;

Technical Note: *A 'splitter duct' performs the initial separation of the air-mass flow between the bypass and core sections of the engine.*

a.4. Uncooled turbine blades, vanes or ''tip shrouds'' designed to operate at a 'gas path temperature' of 1,373 K (1,100 °C) or more;

a.5. Cooled turbine blades, vanes or ''tip-shrouds'', other than those described in 9E003.a.1, designed to operate at a 'gas path temperature' of 1,693 K (1,420 °C) or more;

Technical Note: *'Gas path temperature' is the bulk average gas path total (stagnation) temperature at the leading edge plane of the turbine component when the engine is running in a ''steady state mode'' of operation at the certificated or specified maximum continuous operating temperature.*

a.6. Airfoil-to-disk blade combinations using solid state joining;

a.7. [Reserved]

a.8. 'Damage tolerant' gas turbine engine rotor ''parts'' or ''components'' using powder metallurgy materials controlled by 1C002.b; *or*

Technical Note: *'Damage tolerant' ''parts'' and ''components'' are designed using methodology and substantiation to predict and limit crack growth.*

a.9. [Reserved]

N.B.: *For ''FADEC systems'', see 9E003.h.*

a.10. [Reserved]

N.B.: *For adjustable flow path geometry, see 9E003.i.*

a.11. Hollow fan blades;

b. ''Technology'' ''required'' for the ''development'' or ''production'' of any of the following:

b.1. Wind tunnel aero-models equipped with non-intrusive sensors capable of transmitting data from the sensors to the data acquisition system; *or*

b.2. ''Composite'' propeller blades or prop-fans, capable of absorbing more than 2,000 kW at flight speeds exceeding Mach 0.55;

c. ''Technology'' ''required'' for manufacturing cooling holes, in gas turbine engine ''parts'' or ''components'' incorporating any of the ''technologies'' specified by 9E003.a.1, 9E003.a.2 or 9E003.a.5, and having any of the following:

c.1. Having all of the following:

c.1.a. Minimum 'cross-sectional area' less than 0.45 mm^2;

c.1.b. 'Hole shape ratio' greater than 4.52; *and*

c.1.c. 'Incidence angle' equal to or less than 25°; *or*

c.2. Having all of the following:

c.2.a. Minimum 'cross-sectional area' less than 0.12 mm^2;

c.2.b. 'Hole shape ratio' greater than 5.65; *and*

c.2.c. 'Incidence angle' more than 25°;

Note: *9E003.c does not apply to ''technology'' for manufacturing constant radius cylindrical holes that are straight through and enter and exit on the external surfaces of the component.*

Technical Notes:

1. For the purposes of 9E003.c, the 'cross-sectional area' is the area of the hole in the plane perpendicular to the hole axis.

2. For the purposes of 9E003.c, 'hole shape ratio' is the nominal length of the axis of the hole divided by the square root of its minimum 'cross-sectional area'.

3. For the purposes of 9E003.c, 'incidence angle' is the acute angle measured between the plane tangential to the airfoil surface and the hole axis at the point where the hole axis enters the airfoil surface.

4. Techniques for manufacturing holes in 9E003.c include ''laser'' beam machining, water jet machining, Electro-Chemical Machining (ECM) or Electrical Discharge Machining (EDM).

d. ''Technology'' ''required'' for the ''development'' or ''production'' of helicopter power transfer systems or tilt rotor or tilt wing ''aircraft'' power transfer systems;

e. ''Technology'' for the ''development'' or ''production'' of reciprocating diesel engine ground vehicle propulsion systems having all of the following:

e.1. 'Box volume' of 1.2 m^3 or less;

e.2. An overall power output of more than 750 kW based on 80/1269/EEC, ISO 2534 or national equivalents; *and*

e.3. Power density of more than 700 kW/m^3 of 'box volume';

Technical Note: *'Box volume' is the product of three perpendicular dimensions measured in the following way:*

Length: The length of the crankshaft from front flange to flywheel face;

Width: The widest of any of the following:

a. The outside dimension from valve cover to valve cover;

b. The dimensions of the outside edges of the cylinder heads; or

c. The diameter of the flywheel housing;

Height: The largest of any of the following:

a. The dimension of the crankshaft center-line to the top plane of the valve cover (or cylinder head) plus twice the stroke; or

b. The diameter of the flywheel housing.

f. ''Technology'' ''required'' for the ''production'' of ''specially designed'' ''parts'' or ''components'' for high output diesel engines, as follows:

f.1. ''Technology'' ''required'' for the ''production'' of engine systems having all of the following ''parts'' and ''components'' employing ceramics materials controlled by 1C007:

f.1.a Cylinder liners;

f.1.b. Pistons;

f.1.c. Cylinder heads; *and*

f.1.d. One or more other ''part'' or ''component'' (including exhaust ports, turbochargers, valve guides, valve assemblies or insulated fuel injectors);

f.2. ''Technology'' ''required'' for the ''production'' of turbocharger systems with single-stage compressors and having all of the following:

f.2.a. Operating at pressure ratios of 4:1 or higher;

f.2.b. Mass flow in the range from 30 to 130 kg per minute; *and*

f.2.c. Variable flow area capability within the compressor or turbine sections;

f.3. ''Technology'' ''required'' for the ''production'' of fuel injection systems with a ''specially designed'' multifuel (*e.g.,* diesel or jet fuel) capability covering a viscosity range from diesel fuel (2.5 cSt at 310.8 K (37.8 °C)) down to gasoline fuel (0.5 cSt at 310.8 K (37.8 °C)) and having all of the following:

f.3.a. Injection amount in excess of 230 mm^3 per injection per cylinder; *and*

f.3.b. Electronic control features ''specially designed'' for switching governor characteristics automatically depending on fuel property to provide the same torque characteristics by using the appropriate sensors;

g. ''Technology'' ''required'' for the development'' or ''production'' of 'high output diesel engines' for solid, gas phase or liquid film (or combinations thereof) cylinder wall lubrication and permitting operation to temperatures exceeding 723 K (450 °C), measured on the cylinder wall at the top limit of travel of the top ring of the piston;

Technical Note: *'High output diesel engines' are diesel engines with a specified brake mean effective pressure of 1.8 MPa or more at a speed of 2,300 r.p.m., provided the rated speed is 2,300 r.p.m. or more.*

h. ''Technology'' for gas turbine engine ''FADEC systems'' as follows:

h.1. ''Development'' ''technology'' for deriving the functional requirements for the ''parts'' or ''components'' necessary for the ''FADEC system'' to regulate engine thrust or shaft power (*e.g.,* feedback sensor time constants and accuracies, fuel valve slew rate);

h.2. ''Development'' or ''production'' ''technology'' for control and diagnostic ''parts'' or ''components'' unique to the ''FADEC system'' and used to regulate engine thrust or shaft power;

h.3. ''Development'' ''technology'' for the control law algorithms, including ''source code'', unique to the ''FADEC system'' and used to regulate engine thrust or shaft power;

Note: *9E003.h does not apply to technical data related to engine-''aircraft'' integration required by civil aviation authorities of one or more Wassenaar Arrangement Participating States (See Supplement No. 1 to part 743 of the EAR) to be published for general airline use (e.g., installation manuals, operating instructions, instructions for continued airworthiness) or interface functions (e.g., input/output processing, airframe thrust or shaft power demand).*

i. ''Technology'' for adjustable flow path systems designed to maintain engine stability

for gas generator turbines, fan or power turbines, or propelling nozzles, as follows:

i.1. ''Development'' ''technology'' for deriving the functional requirements for the ''parts'' or ''components'' that maintain engine stability;

i.2. ''Development'' or ''production'' ''technology'' for ''parts'' or ''components'' unique to the adjustable flow path system and that maintain engine stability;

i.3. ''Development'' ''technology'' for the control law algorithms, including ''source code'', unique to the adjustable flow path system and that maintain engine stability;

Note: *9E003.i does not apply to ''technology'' for any of the following:*

a. Inlet guide vanes;

b. Variable pitch fans or prop-fans;

c. Variable compressor vanes;

d. Compressor bleed valves; or

e. Adjustable flow path geometry for reverse thrust.

j. ''Technology'' ''required'' for the ''development'' of wing-folding systems designed for fixed-wing ''aircraft'' powered by gas turbine engines.

N.B.: *For ''technology'' ''required'' for the ''development'' of wing-folding systems designed for fixed-wing ''aircraft'' specified in USML Category VIII (a), see USML Category VIII (i).*

k. ''Technology'' not otherwise controlled in 9E003.a.1 through a.8, a.10, and .h and used in the ''development'', ''production'', or overhaul of hot section ''parts'' or ''components'' of civil derivatives of military engines controlled on the U.S. Munitions List.

* * * * *

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–26638 Filed 12–3–20; 8:45 am]

BILLING CODE 3510–33–P

Reader Aids

Federal Register

Vol. 85, No. 234

Friday, December 4, 2020

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, DECEMBER

CFR PARTS AFFECTED DURING DECEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List November 3, 2020

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://listserv.gsa.gov/cgi-bin/wa.exe?SUBED1=PUBLAWS-L&A=1*

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.