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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2020–0179]

RIN 3150–AK51

List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM UMAX Canister Storage System, Certificate of Compliance No. 1040, Amendment No. 4

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its spent fuel storage regulations by revising the Holtec International HI–STORM UMAX Canister Storage System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 4 to Certificate of Compliance No. 1040. Amendment No. 4 revises the certificate of compliance to update the technical specifications for radiation protection regarding the dose rate limit for the vertical ventilated module lid, update the technical specifications for the vent blockage limiting condition for operation, and add a Type 1 version of multi-purpose canister MPC–37.

DATES: This direct final rule is effective January 25, 2021, unless significant adverse comments are received by December 9, 2020. If this direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0179. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff. For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christian J. Jacobs, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6825; email: *Christian.Jacobs@nrc.gov* or Gerry L. Stirewalt, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–3698; email: *Gerry.Stirewalt@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0179 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0179.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2020–0179 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information

before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

This rule is limited to the changes contained in Amendment No. 4 to Certificate of Compliance No. 1040 and does not include other aspects of the Holtec International HI–STORM UMAX Canister Storage System cask design. The NRC is using the ''direct final rule procedure'' to issue this amendment because it represents a limited and routine change to an existing certificate of compliance that is expected to be non-controversial. The NRC has determined that, with the requested changes, adequate protection of public health and safety will continue to be reasonably assured. The amendment to the rule will become effective on January 25, 2021. However, if the NRC receives any significant adverse comments on this direct final rule by December 9, 2020, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule, certificate of compliance, or technical specifications.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on March 6, 2015 (80 FR 12073), as corrected (80 FR 15679; March 25, 2015), that approved the Holtec International HI–STORM UMAX Canister Storage System and added it to the list of NRC-approved cask designs in § 72.214, ''List of approved spent fuel storage casks,'' as Certificate of Compliance No. 1040.

IV. Discussion of Changes

On September 28, 2018, Holtec International submitted a request to amend Certificate of Compliance No. 1040 for the HI–STORM UMAX Canister Storage System. Holtec International supplemented its request on the following dates: May 21, 2019; November 1, 2019; December 20, 2019; March 30, 2020; and April 13, 2020. Amendment No. 4 revises the certificate of compliance to (1) update the technical specifications for radiation protection regarding the dose rate limit for the vertical ventilated module lid, (2) update the technical specifications for the vent blockage limiting condition for operation, and (3) add a Type 1 version of multi-purpose canister MPC–37.

As documented in the preliminary safety evaluation report, the NRC performed a safety evaluation of the proposed certificate of compliance amendment request. The NRC determined that this amendment does not reflect a significant change in design or fabrication of the cask. Specifically, the NRC determined that the design of the cask would continue to maintain confinement, shielding, and criticality control in the event of each evaluated accident condition. This amendment does not reflect a significant change in design or fabrication of the cask. In addition, any resulting occupational exposure or offsite dose rates from the implementation of Amendment No. 4 would remain well within the limits specified by 10 CFR part 20, ''Standards for Protection Against Radiation.'' Thus, the NRC found there will be no significant change in the types or amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents.

The NRC determined that the amended Holtec International HI–STORM UMAX Canister Storage System cask design, when used under the conditions specified in the certificate of compliance, the technical specifications, and the NRC's regulations, will meet the requirements of 10 CFR part 72; therefore, adequate protection of public health and safety will continue to be reasonably assured. When this direct final rule becomes effective, persons who hold a general license under § 72.210 may, consistent with license conditions under § 72.212, load spent nuclear fuel into Holtec International HI–STORM UMAX Canister Storage System casks that meet the criteria of Amendment No. 4 to Certificate of Compliance No. 1040.

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC revises the Holtec International HI–STORM UMAX Canister Storage System cask design listed in § 72.214, ''List of approved spent fuel storage casks.'' This action does not constitute the establishment of a standard that

contains generally applicable requirements.

VI. Agreement State Compatibility

Under the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017, and published in the **Federal Register** on October 18, 2017 (82 FR 48535), this rule is classified as Compatibility Category NRC—Areas of Exclusive NRC Regulatory Authority. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR chapter I. Therefore, compatibility is not required for program elements in this category. Although an Agreement State may not adopt program elements reserved to the NRC, and the Category ''NRC'' does not confer regulatory authority on the State, the State may wish to inform its licensees of certain requirements by means consistent with the State's administrative procedure laws.

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

VIII. Environmental Assessment and Finding of No Significant Impact

Under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' the NRC has determined that this direct final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC has made a finding of no significant impact based on the basis of this environmental assessment.

A. The Action

The action is to amend § 72.214 by revising the Holtec International HI–STORM UMAX Canister Storage System listing in the ''List of approved spent fuel storage casks'' to include Amendment No. 4 to Certificate of Compliance No. 1040.

B. The Need for the Action

This direct final rule amends the certificate of compliance for the Holtec International HI–STORM UMAX Canister Storage System design within the list of approved spent fuel storage casks to allow power reactor licensees to store spent fuel at reactor sites in casks with the approved modifications under a general license. Specifically, Amendment No. 4 revises the certificate of compliance to (1) update the technical specifications for radiation protection regarding the dose rate limit for the vertical ventilated module lid, (2) update the technical specifications for the vent blockage limiting condition for operation, and (3) add a Type 1 version of multi-purpose canister MPC–37.

C. Environmental Impacts of the Action

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent fuel under a general license in cask designs approved by the NRC. The potential environmental impact of using NRC-approved storage casks was analyzed in the environmental assessment for the 1990 final rule. The environmental assessment for Amendment No. 4 tiers off the environmental assessment for the July 18, 1990, final rule. Tiering on past environmental assessments is a standard process under the National Environmental Policy Act of 1969, as amended. The Holtec International HI–STORM UMAX Canister Storage System is designed to mitigate the effects of design basis accidents that could occur during storage. Design basis accidents account for human-induced events and the most severe natural phenomena reported for the site and surrounding area. Postulated accidents analyzed for an independent spent fuel storage installation, the type of facility at which a holder of a power reactor operating license would store spent fuel in casks in accordance with 10 CFR part 72, can include tornado winds and tornado-generated missiles, a design basis earthquake, a design basis flood, an accidental cask drop, lightning effects, fire, explosions, and other incidents.

The design of the cask would provide confinement, shielding, and criticality control in the event of each evaluated accident condition. If confinement, shielding, and criticality control are maintained, the environmental impacts resulting from an accident would be insignificant. This amendment does not reflect a significant change in design or fabrication of the cask. Because there are no significant design or process changes, any resulting occupational exposure or offsite dose rates from the implementation of Amendment No. 4 would remain well within the 10 CFR part 20 limits. Therefore, the proposed certificate of compliance changes will not result in any radiological or non-radiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990, final rule. There will be no significant change in the types or significant revisions in the amounts of any effluent released, no significant increase in the individual or cumulative radiation exposures, and no significant increase in the potential for, or consequences from, radiological accidents. The NRC documented its safety findings in the preliminary safety evaluation report.

D. Alternative to the Action

The alternative to this action is to deny approval of Amendment No. 4 and not issue the direct final rule. Consequently, any 10 CFR part 72 general licensee that seeks to load spent nuclear fuel into the Holtec International HI–STORM UMAX Canister Storage System in accordance with the changes described in proposed Amendment No. 4 would have to request an exemption from the requirements of §§ 72.212 and 72.214. Under this alternative, interested licensees would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee. The environmental impacts would be the same as the proposed action.

E. Alternative Use of Resources

Approval of Amendment No. 4 to Certificate of Compliance No. 1040 would result in no irreversible commitment of resources.

F. Agencies and Persons Contacted

No agencies or persons outside the NRC were contacted in connection with the preparation of this environmental assessment.

G. Finding of No Significant Impact

The environmental impacts of the action have been reviewed under the requirements in the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51. Based on the foregoing environmental assessment, the NRC concludes that this direct final rule, entitled ''List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM UMAX Canister Storage System, Certificate of Compliance No. 1040, Amendment No. 4'' will not have a significant effect on the human

environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this direct final rule.

IX. Paperwork Reduction Act Statement

This direct final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval number 3150–0132.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

X. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and Holtec International. These entities do not fall within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

XI. Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if (1) it notifies the NRC in advance, (2) the spent fuel is stored under the conditions specified in the cask's certificate of compliance, and (3) the conditions of the general license are met. A list of NRC-approved cask designs is contained in § 72.214. On March 6, 2015 (80 FR 12073), as corrected (80 FR 15679; March 25, 2015), the NRC issued an amendment to 10 CFR part 72 that approved the Holtec International HI–STORM UMAX Canister Storage System design by adding it to the list of NRC-approved cask designs in § 72.214.

On September 28, 2018, and as supplemented on May 21, 2019, November 1, 2019, December 20, 2019, March 30, 2020, and April 13, 2020, Holtec International submitted a request to amend the HI–STORM UMAX Canister Storage System as described in Section IV, ''Discussion of Changes,'' of this document.

The alternative to this action is to withhold approval of Amendment No. 4 and to require any 10 CFR part 72 general licensee seeking to load spent nuclear fuel into the Holtec International HI–STORM UMAX Canister Storage System under the changes described in Amendment No. 4 to request an exemption from the requirements of §§ 72.212 and 72.214. Under this alternative, each interested 10 CFR part 72 licensee would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

Approval of this direct final rule is consistent with previous NRC actions. Further, as documented in the preliminary safety evaluation report and environmental assessment, this direct final rule will have no adverse effect on public health and safety or the environment. This direct final rule has no significant identifiable impact or benefit on other government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of this direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory; therefore, this action is recommended.

XII. Backfitting and Issue Finality

The NRC has determined that the backfit rule (§ 72.62) does not apply to this direct final rule. Therefore, a backfit analysis is not required. This direct final rule revises Certificate of Compliance No. 1040 for the Holtec International HI–STORM UMAX Canister Storage System, as currently listed in § 72.214. The revision consists of the changes in Amendment No. 4 previously described, as set forth in the revised certificate of compliance and technical specifications.

Amendment No. 4 to Certificate of Compliance No. 1040 for the Holtec International HI–STORM UMAX Canister Storage System was initiated by Holtec International and was not submitted in response to new NRC requirements, or an NRC request for amendment. Amendment No. 4 applies only to new casks fabricated and used under Amendment No. 4. These changes do not affect existing users of the Holtec International HI–STORM UMAX Canister Storage System, and the current Amendment No. 2 continues to be effective for existing users. Amendment No. 3 to Certificate of Compliance No. 1040 has not been issued. While existing users of this storage system may comply with the new requirements in Amendment No. 4, this would be a voluntary decision on the part of existing users.

For these reasons, Amendment No. 4 to Certificate of Compliance No. 1040 does not constitute backfitting under § 72.62 or § 50.109(a)(1), or otherwise represent an inconsistency with the issue finality provisions applicable to combined licenses in 10 CFR part 52. Accordingly, the NRC has not prepared a backfit analysis for this rulemaking.

XIII. Congressional Review Act

This direct final rule is not a rule as defined in the Congressional Review Act.

XIV. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Document	ADAMS package accession No.
Letter from Holtec International to NRC submitting the Amendment No. 4 Request for HI–STORM UMAX Canister Storage System Certificate of Compliance No. 1040, September 28, 2018.	ML18285A820.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, May 21, 2019.	ML19144A140.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, November 1, 2019.	ML19311C514.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, December 20, 2019.	ML20002A425.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, March 30, 2020.	ML20104C014.

Document	ADAMS package accession No.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, April 13, 2020.	ML20111A237.
User Need Memorandum to J. Cai from J. McKirgan with Proposed Certificate of Compliance No. 1040, Amendment No. 4; Associated Proposed Technical Specifications; and the Preliminary Safety Evaluation Report, July 21, 2020.	ML20161A087.

The NRC may post materials related to this document, including public comments, on the Federal Rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2020–0179. The Federal Rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC–2020–0179); (2) click the ''Sign up for Email Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance No. 1040 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1040.
Initial Certificate Effective Date: April 6, 2015.
Amendment Number 1 Effective Date: September 8, 2015.
Amendment Number 2 Effective Date: January 9, 2017.
Amendment Number 3 [RESERVED]
Amendment Number 4 Effective Date: January 25, 2021.
SAR Submitted by: Holtec International, Inc.
SAR Title: Final Safety Analysis Report for the Holtec International HI–STORM UMAX Canister Storage System.
Docket Number: 72–1040.
Certificate Expiration Date: April 6, 2035.
Model Number: MPC–37, MPC–89.

* * * * *

Dated October 21, 2020.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2020–24320 Filed 11–6–20; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 327

RIN 3064–AF64

Assessments; Corrections

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Correcting amendments.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC) is making technical amendments to its rules governing deposit insurance assessments in two places to conform regulatory text to the text that was adopted by the FDIC Board of Directors (FDIC Board). Due to publishing errors, incorrect text was printed in the **Federal Register** and the Code of Federal Regulations. The first amendment will conform the value of the weighted charge-off rate for loans secured by nonfarm nonresidential properties that appears in the FDIC's assessment regulations to the charge-off rate adopted by the FDIC Board. The second amendment will conform a footnote that defines two terms in the descriptions of the counterparty measures for purposes of deposit insurance assessments to the language adopted by the FDIC Board. The technical amendments will not affect assessments previously paid by insured depository institutions (IDIs) or assessments paid by IDIs in the future.

DATES: Effective November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Daniel Hoople, Senior Financial Economist, Banking and Regulatory Policy Section, Division of Insurance and Research, (202) 898–3835, *dhoople@fdic.gov;* Nefretete Smith, Counsel, Legal Division, (202) 898–6851, *nefsmith@fdic.gov.*

SUPPLEMENTARY INFORMATION:

I. Technical Amendment Regarding the Loan Mix Index

The FDIC assesses all IDIs [1] an amount for deposit insurance equal to the institution's deposit insurance assessment base multiplied by its risk-based assessment rate.[2] On May 20, 2016, the FDIC published a final rule (2016 final rule) that refined the deposit insurance assessment system for established small IDIs.[3] Under the 2016 final rule, one of the measures used to calculate the assessment rate of an established small IDI is the loan mix index, a measure of the extent to which an IDI's total assets include higher-risk categories of loans.

This technical amendment corrects the historical weighted charge-off rate for loans secured by nonfarm nonresidential properties, one of the categories of loans used in the loan mix index, that is currently published in the Code of Federal Regulations. Due to an inadvertent publishing error, the rate

[1] As used in this notice, the term ''insured depository institution'' has the same meaning as the definition used in Section 3 of the Federal Deposit Insurance Act (FDI Act), 12 U.S.C. 1813(c)(2).

[2] *See generally* 12 CFR 327.3(b)(1).

[3] 81 FR 32179 (May 20, 2016).

that appeared in the **Federal Register** notice for the final rule on May 20, 2016 (81 FR 32179), 0.7289274, differs from the historical weighted average industrywide charge-off rate that the FDIC Board adopted on April 26, 2016, and that the FDIC uses to calculate an IDI's loan mix index, 0.7286274, by three ten-thousandths of a percentage point. The technical amendment will not affect assessments previously paid by IDIs, or assessments paid by IDIs in the future, because the value for loans secured by nonfarm nonresidential properties that the FDIC uses to calculate the loan mix index is the value adopted by the FDIC Board in the 2016 final rule.

II. Technical Amendment Regarding Description of Scorecard Measures for Highly Complex Institutions

In 2014, the FDIC published a final rule (2014 final rule) that, among other things, requires highly complex institutions—generally, those with at least $50 billion in total assets (or owned by a parent holding company with at least $500 billion in assets) or those defined as processing banks or trust companies—to measure counterparty exposure for deposit insurance assessment purposes using the Basel III standardized approach.[4] Counterparty exposure is captured in two measures—the ratio of top 20 counterparty exposures to Tier 1 capital and reserves and the ratio of the largest counterparty exposure to Tier 1 capital and reserves (collectively, the counterparty exposure measures)—which are used to determine a highly complex institution's assessment rate.

The 2014 final rule, among other things, revised footnote 2 in section VI., Description of Scorecard Measures, in appendix A to subpart A of the assessment regulations to define two terms—''secured financing transactions'' (SFTs) and ''default fund contribution''—used in the descriptions of the counterparty exposure measures. Due to an inadvertent publishing error, the revisions to the second footnote that were adopted by the FDIC Board on November 18, 2014, and published in the **Federal Register** on November 26, 2014, do not appear in the current version of the Code of Federal Regulations.

This technical amendment replaces the footnote that appears in the Code of Federal Regulations with the version adopted by the FDIC Board in the 2014 final rule. The technical amendment will not affect assessments previously paid by IDIs, or assessments paid by IDIs in the future, because the definitions the FDIC uses to calculate the counterparty exposure measures are the definitions adopted by the FDIC Board in the 2014 final rule.

[4] 79 FR 70427 (Nov. 26, 2014).

List of Subjects in 12 CFR Part 327

Bank deposit insurance, Banks, Banking, Savings associations.

For the reasons stated in the preamble, the FDIC makes the following correcting amendments to 12 CFR part 327:

PART 327—ASSESSMENTS

■ 1. The authority citation for part 327 continues to read as follows:

Authority: 12 U.S.C. 1813, 1815, 1817–19, 1821.

■ 2. In § 327.16, revise paragraph (a)(1)(ii)(B) to read as follows:

§ 327.16 Assessment pricing methods—beginning the first assessment period after June 30, 2016, where the reserve ratio of the DIF as of the end of the prior assessment period has reached or exceeded 1.15 percent.

(a) * * *

(1) * * *

(ii) * * *

(B) *Definition of loan mix index.* The Loan Mix Index assigns loans in an institution's loan portfolio to the categories of loans described in the following table. The Loan Mix Index is calculated by multiplying the ratio of an institution's amount of loans in a particular loan category to its total assets by the associated weighted average charge-off rate for that loan category, and summing the products for all loan categories. The table gives the weighted average charge-off rate for each category of loan. The Loan Mix Index excludes credit card loans.

LOAN MIX INDEX CATEGORIES AND WEIGHTED CHARGE-OFF RATE PERCENTAGES

	Weighted charge-off rate (percent)
Construction & Development	4.4965840
Commercial & Industrial	1.5984506
Leases	1.4974551
Other Consumer	1.4559717
Real Estate Loans Residual	1.0169338
Multifamily Residential	0.8847597
Nonfarm Nonresidential	0.7286274
1–4 Family Residential	0.6973778
Loans to Depository Banks	0.5760532
Agricultural Real Estate	0.2376712
Agriculture	0.2432737

* * * * *

■ 3. In appendix A to subpart A of part 327, revise footnote 2 of the table under the section ''VI. Description of Scorecard Measures,'' to read as follows:

Appendix A to Subpart A of Part 327—Method To Derive Pricing Multipliers and Uniform Amount

* * * * *

VI. Description of Scorecard Measures

* * * * *

[1] * * *

[2] SFTs include repurchase agreements, reverse repurchase agreements, security lending and borrowing, and margin lending transactions, where the value, of the transactions depends on market valuations and the transactions are often subject to margin agreements. The default fund contribution is the funds contributed or commitments made by a clearing member to a central counterparty's mutualized loss sharing arrangement. The other terms used in this description are as defined in 12 CFR part 324, subparts A and D, unless defined otherwise in 12 CFR part 327.

* * * * *

■ 4. In part I of appendix E to subpart A of part 327, revise the table titled ''Loan Mix Index Categories and Weighted Charge-Off Rate Percentages'' to read as follows:

Appendix E to Subpart A of Part 327—Mitigating the Deposit Insurance Assessment Effect of Participation in the Money Market Mutual Fund Liquidity Facility, the Paycheck Protection Program Liquidity Facility, and the Paycheck Protection Program

* * * * *

LOAN MIX INDEX CATEGORIES AND WEIGHTED CHARGE-OFF RATE PERCENTAGES

	Weighted charge-off rate percent
Construction & Development	4.4965840
Commercial & Industrial	1.5984506
Leases	1.4974551
Other Consumer	1.4559717
Real Estate Loans Residual	1.0169338
Multifamily Residential	0.8847597
Nonfarm Nonresidential	0.7286274
1–4 Family Residential	0.6973778
Loans to Depository banks	0.5760532
Agricultural Real Estate	0.2376712
Agriculture	0.2432737

* * * * *

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on October 19, 2020.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2020–23492 Filed 11–6–20; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0979; Project Identifier MCAI–2020–01313–E; Amendment 39–21317; AD 2020–23–01]

RIN 2120–AA64

Airworthiness Directives; GE Aviation Czech s.r.o. (Type Certificate Previously Held by WALTER Engines a.s., Walter a.s., and MOTORLET a.s.) Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all GE Aviation Czech s.r.o. (GEAC) M601D–11, M601E–11, M601E–11A, M601E–11AS, M601E–11S, M601F, H75–200, H80–100, H80–200, and H85–200 model turboprop engines. This AD was prompted by reports of engine power fluctuations occurring during ground tests. This AD requires the removal and replacement of the fuel control unit (FCU). The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 24, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 24, 2020.

The FAA must receive comments on this AD by December 24, 2020.

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

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

For service information identified in this final rule, contact GE Aviation Czech s.r.o., Beranových 65, 199 02 Praha 9—Letňany, Czech Republic; phone: +420 222 538 111; fax +420 222 538 222. 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–2020–0979.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0979; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; fax: (781) 238–7199; email: *barbara.caufield@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2020–0201R1, dated September 25, 2020 (referred to after this as ''the MCAI''), to address an unsafe condition for the specified products. The MCAI states:

> Several occurrences of engine power fluctuations have been reported during ground tests on engines equipped with an affected part. The investigation results determined that one or more rubber cuff sealings of the cage reinforcement inside the main metering valve of the FCU was wrongly installed, which reduced the cuff ability to properly seal the FCU working pressure.
>
> This condition, if not corrected, may lead to engine surge, fluctuations, or loss of engine power, possibly resulting in loss of control of control of the aeroplane.
>
> To address this potential unsafe condition, GEAC issued the ASB, providing replacement instructions, and EASA issued Emergency AD 2020–0201–E to require, for engines having an affected part installed, replacement with a serviceable part. That [EASA] AD also prohibited (re)installation of an affected part.
>
> Since that [EASA] AD was issued, it was discovered that an FCU s/n was incorrectly specified in the ASB and, consequently, wrongly quoted in the EASA AD. GEAC revised the ASB to correct that error and this [EASA] AD is revised to amend Appendix 1 (Group 3, s/n 903004 instead of 903008) accordingly.

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–2020–0979.

FAA's Determination

This product has been approved by EASA and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI. The FAA is issuing this AD because the agency evaluated all the relevant information provided by EASA and has determined that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed GE Aviation Czech Alert Service Bulletin (ASB) ASB–H75–73–00–00–0038 [01], ASB–H80–73–00–00–0074 [01], ASB–H85–73–00–00–0032 [01], ASB–M601D–73–00–00–0066 [01], ASB–M601E–73–00–00–0097 [01], ASB–M601F–73–00–00–0050 [01], and ASB–M601T–73–00–00–0040 [01] (single document; formatted as service bulletin identifier [revision number]), dated September 24, 2020. The ASB describes procedures for removing and replacing the FCU and identifies the affected FCUs. 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**.

AD Requirements

This AD requires the removal and replacement of the FCU.

Differences Between This AD and the MCAI

EASA AD 2020–0201R1, dated September 25, 2020, applies to GEAC M601D, M601D–1, M601D–11, M601D–11NZ, M601E, M601E–11, M601E–11A, M601E–11AS, M601E–11S, M601E–21, M601F, M601F–22, M601F–32, M601FS, M601T, H75–200, H80–100, H80–200, and H85–200 model turboprop engines. This AD does not include GEAC M601D, M601D–1, M601D–11NZ, M601E, M601E–21, M601F–22, M601F–32, M601FS, and M601T model turboprop engines as they are not type certificated in the U.S.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency,

upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, Section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule. During ground tests performed by the manufacturer on engines equipped with affected FCUs, several occurrences of engine power fluctuations were reported. After investigation, the manufacturer determined that one or more rubber cuff sealings of the cage reinforcement inside the main metering valve of the FCU was incorrectly installed, which reduced the cuff sealing's ability to properly seal the FCU working pressure. This unsafe condition, caused by a manufacturing quality issue, may result in loss of engine thrust control and reduced control of the airplane.

FCUs installed on Group 1 engines have the highest risk of malfunction. To maintain an acceptable level of safety, these FCUs must be replaced within 10 flight hours (FHs) after the effective date of this AD. FCUs installed on Group 2 and Group 3 engines have a lower risk of malfunction than those installed on Group 1 engines. Therefore, for Group 2 engines, FCUs must be replaced within 50 FHs or 60 days after the effective day of this AD, whichever occurs first. For Group 3 engines, FCUs must be replaced within 100 FHs or 180 days after the effective date of this AD, whichever occurs first.

The FAA considers the removal of the affected FCUs to be an urgent safety issue. Accordingly, notice and opportunity for prior public comment are impracticable, pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forego notice and comment.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include the docket number FAA–2020–0979 and Project Identifier MCAI–2020–01313–E at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, 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 final rule 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 final rule.

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 AD 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 AD, 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 AD. Submissions containing CBI should be sent to Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 12 engines installed on airplanes of U.S. registry.

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
Remove and replace FCU	5 work-hours × $85 per hour = $425	$25,000	$25,425	$305,100

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

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 adding the following new airworthiness directive:

2020–23–01 GE Aviation Czech s.r.o (Type Certificate previously held by WALTER Engines a.s., Walter a.s., and MOTORLET a.s.): Amendment 39–21317; Docket No. FAA–2020–0979; Project Identifier MCAI–2020–01313–E.

(a) Effective Date

This airworthiness directive (AD) is effective November 24, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all GE Aviation Czech s.r.o. (GEAC) M601D–11, M601E–11, M601E–11A, M601E–11AS, M601E–11S, M601F, H75–200, H80–100, H80–200, and H85–200 model turboprop engines, with a fuel control unit (FCU) part number (P/N) and serial number (S/N) listed in Appendix 1—Affected Parts of GE Aviation Czech Alert Service Bulletin (ASB) ASB–H75–73–00–00–0038 [01], ASB–H80–73–00–00–0074 [01], ASB–H85–73–00–00–0032 [01], ASB–M601D–73–00–00–0066 [01], ASB–M601E–73–00–00–0097 [01], ASB–M601F–73–00–00–0050 [01], and ASB–M601T–73–00–00–0040 [01] (single document; formatted as service bulletin identifier [revision number]), dated September 24, 2020 (the ASB), installed.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by incorrect installation by the manufacturer of one or more rubber cuff sealings of the cage reinforcement inside the main metering valve of the FCU, which reduces the cuff sealing's ability to properly seal the FCU working pressure. The FAA is issuing this AD to prevent the malfunction of the FCU, which could cause engine parameter oscillation or overshoots. The unsafe condition, if not addressed, could result in loss of engine thrust control and reduced control of the airplane.

(f) Compliance

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

(g) Required Actions

Before exceeding the applicable compliance time in Table 1 to paragraph (g) of this AD, remove the affected FCU and replace it with a part eligible for installation using the Accomplishment Instructions, paragraph 2, of the ASB.

Table 1 to Paragraph (g) – FCU Replacement

Engine Group	Compliance Time (after the effective date of this AD)
Group 1 engine	Within 10 flight hours (FHs)
Group 2 engine	Within 50 FHs or 60 days, whichever occurs first
Group 3 engine	Within 100 FHs or 180 days, whichever occurs first

(h) Installation Prohibition

After the effective date of this AD, do not install onto any engine an affected FCU with a P/N and S/N identified in Appendix 1—Affected Parts of the ASB.

(i) No Repair Requirement

The repair requirement in the Accomplishment Instructions, paragraph 2, of the ASB is not required by this AD.

(j) Definitions

(1) For the purpose of this AD, a ''part eligible for installation'' is a FCU with a P/N and S/N that is not identified in Appendix 1—Affected Parts of the ASB.

(2) For the purpose of this AD, a ''Group 1 engine'' is a GEAC model turboprop engine that has a FCU P/N and S/N listed in Appendix 1—Affected Parts, Group 1, of the ASB.

(3) For the purpose of this AD, a ''Group 2 engine'' is a GEAC model turboprop engine that has a FCU P/N and S/N listed in Appendix 1—Affected Parts, Group 2, of the ASB.

(4) For the purpose of this AD, a ''Group 3 engine is a GEAC model turboprop engine that has a FCU P/N and S/N listed in Appendix 1—Affected Parts, Group 3, of the ASB.

(k) 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.

(l) Related Information

For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7146; fax: (781) 238–7199; email: *barbara.caufield@faa.gov.*

(m) 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) GE Aviation Czech Alert Service Bulletin (ASB) ASB–H75–73–00–00–0038 [01], ASB–H80–73–00–00–0074 [01], ASB–H85–73–00–00–0032 [01], ASB–M601D–73–00–00–0066 [01], ASB–M601E–73–00–00–0097 [01], ASB–M601F–73–00–00–0050 [01], and ASB–M601T–73–00–00–0040 [01] (single document; formatted as service bulletin identifier [revision number]), dated September 24, 2020.

(ii) [Reserved]

(3) For GE Aviation Czech service information identified in this AD, contact GE Aviation Czech s.r.o., Beranových 65, 199 02 Praha 9—Letňany, Czech Republic; phone: +420 222 538 111.

(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 October 27, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–24794 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0898; Project Identifier AD–2020–01284–T; Amendment 39–21320; AD 2020–23–04]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Gulfstream Aerospace Corporation (Gulfstream) Model GVII–G500 and Model GVII–G600 airplanes. This AD requires revising your existing airplane flight manual (AFM) and airplane maintenance manual (AMM) to include information pertaining to the fuel boost pump. This AD was prompted by a report of misassembled impellers onto the shaft of the fuel boost pump during production. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 24, 2020.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 24, 2020.

The FAA must receive comments on this AD by December 24, 2020.

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

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

For service information identified in this final rule, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402; phone: (800) 810–4853; email: *pubs@gulfstream.com;* website: *https://www.gulfstream.com/en/customer-support/.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0898.

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–2020–0898; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, 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: Jared Meyer, Aerospace Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5534; fax: (404) 474–5605; email: *jared.meyer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA was notified by Gulfstream of the possibility of misassembled impellers onto the shaft of fuel boost pumps used in the production of GVII–G500 and GVII–G600 airplanes. The supplier of fuel boost pumps discovered two misassembled fuel boost pumps on two different make/models of non-Gulfstream aircraft. The Gulfstream GVII–G500 and GVII–G600 fuel boost pumps are very similar in design and are manufactured in the same facility using the same manufacturing processes, so the same condition could exist on the Gulfstream fuel boost pumps.

A misassembled fuel boost pump could result in a woodruff key becoming dislodged and causing friction between static and rotating components internal to the fuel boost pump. This friction could generate heat or sparks inside the fuel tank, which, if the pump were to run dry, could result in a fuel tank fire or fuel tank explosion.

The unsafe condition, if not addressed, could result in a potential source of ignition in the fuel tank and may lead to fire or explosion.

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following AFM supplements, which contain new warnings about operating the boost pumps with empty fuel tanks for the Abnormal Procedures and Emergency Procedures sections of the AFM. These documents are distinct because they pertain to different airplane models:

- Gulfstream Aerospace GVII–G500 Airplane Flight Manual Supplement No. GVII–G500 (Issue 1)–2020–05, dated September 8, 2020;
- Gulfstream Aerospace GVII–G500 Airplane Flight Manual Supplement No. GVII–G500–2020–06, dated September 8, 2020; and
- Gulfstream Corporation GVII–G600 Airplane Flight Manual Supplement No. GVII–G600–2020–06 dated September 8, 2020.

The FAA also reviewed the following AMM documents, which contain revised maintenance procedures pertaining to the fuel boost pump. These documents are distinct since they apply to different airplane models. Although the documents have the watermarked words ''advance copy'' on each page of the document, these are not advance draft copies but final versions of temporary revisions to the AMM, pending incorporation into the AMM at the next revision.

- GVII–G500 Maintenance Manual 12–13–01 Defueling Procedure—Defuel, dated August 31, 2020;
- GVII–G500 Maintenance Manual 28–26–04 Fuel Boost Pump—Prime, dated August 31, 2020;
- GVII–G600 Maintenance Manual 12–13–01 Defueling Procedure—Defuel, dated August 31, 2020;
- GVII–G600 Maintenance Manual 28–26–04 Fuel Boost Pump—Prime, dated August 31, 2020;
- GVII–G600 Maintenance Manual 28–26–04 Fuel Boost Pump—Removal/Installation, dated August 31, 2020; and
- GVII–G600 Maintenance Manual 28–26–05 Fuel Boost Pump Canister—Removal/Installation, dated August 31, 2020.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

AD Requirements

This AD requires revising the existing AFM for your airplane by adding new warnings to the Abnormal Procedures and Emergency Procedures sections. Revising the existing AFM for your airplane is not considered a maintenance action and therefore may be performed by the owner/operator (pilot) holding at least a private pilot certificate. The pilot must record compliance in the aircraft maintenance records in accordance with 14 CFR 43.9(a)(1) through (4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417.

This AD also requires revising the existing AMM for your airplane by replacing maintenance procedures pertaining to the fuel boost pump.

Interim Action

The FAA considers this AD an interim action. The design approval holder is currently working on a modification that will address the unsafe condition identified in this AD. Once this modification action is developed, FAA-approved, and available, the FAA will consider additional rulemaking.

Justification For Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies foregoing notice and comment prior to adoption of this rule because misassembled fuel boost pump components could generate heat or sparks leading to a potential fuel tank explosion. If an operator or maintenance personnel were to run fuel boost pump dry, it could result in fuel tank fire or explosion. The FAA determined that the actions necessary to correct this condition must be accomplished within 14 days. Therefore, the FAA finds good cause that notice and opportunity for prior public comment are impracticable pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. The FAA invites you to send any written relevant data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include Docket No. FAA–2020–0898 and Project Identifier AD–2020–01284–T at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, 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 final rule 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 final rule.

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 AD 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 AD, 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 AD. Submissions containing CBI should be sent to Jared Meyer, Aerospace Engineer, Atlanta ACO Branch, FAA, 107 Charles W. Grant Pkwy, Atlanta, GA 30354. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Costs of Compliance

The FAA estimates that this AD affects 80 airplanes of U.S. registry.

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
Revise the AMM	1 work-hour × $85 per hour = $85	Not applicable	$85	$6,800
Revise the AFM	1 work-hour × $85 per hour = $85	Not applicable	85	6,800

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 Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2020–23–04 Gulfstream Aerospace Corporation: Amendment 39–21320; Docket No. FAA–2020–0898; Project Identifier AD–2020–01284–T.

(a) Effective Date

This airworthiness directive (AD) is effective November 24, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace Corporation Model GVII–G500 airplanes, serial numbers 72001 through 72064, and Model GVII–G600 airplanes, serial numbers 73001 through 73043, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 2822, Fuel Boost Pump.

(e) Unsafe Condition

This AD was prompted by a report of misassembled impellers onto the shaft of the fuel boost pump during production. The FAA is issuing this AD to prevent the ignition of flammable vapors in the fuel tank as a result of frictional heating or sparks caused by a dislodged woodruff key inside the fuel boost pump. This unsafe condition, if not addressed, could result in a potential source of ignition in the fuel tank and consequent fire or explosion.

(f) Compliance

You must comply with this AD within 14 days after the effective date of this AD, unless already done.

(g) Required Actions

(1) Revise your existing airplane maintenance manual (AMM) by replacing the procedures listed in paragraphs (g)(1)(i) through (vi) of this AD, as applicable for your model airplane.

(i) GVII–G500 Maintenance Manual 12–13–01 Defueling Procedure—Defuel, dated August 31, 2020;

(ii) GVII–G500 Maintenance Manual 28–26–04 Fuel Boost Pump—Prime, dated August 31, 2020;

(iii) GVII–G600 Maintenance Manual 12–13–01 Defueling Procedure—Defuel, dated August 31, 2020;

(iv) GVII–G600 Maintenance Manual 28–26–04 Fuel Boost Pump—Prime, dated August 31, 2020;

(v) GVII–G600 Maintenance Manual 28–26–04 Fuel Boost Pump—Removal/ Installation, dated August 31, 2020; and

(vi) GVII–G600 Maintenance Manual 28–26–05 Fuel Boost Pump Canister—Removal/ Installation, dated August 31, 2020.

(2) Revise your existing airplane flight manual (AFM) by including in the AFM the airplane flight manual supplement (AFMS) listed in paragraph (g)(2)(i), (ii) or (iii) of this AD that is applicable to your model airplane. Using a later AFM revision with information identical to that contained in the AFMS specified for your airplane is acceptable for compliance with the requirement of this paragraph.

(i) Gulfstream Aerospace GVII–G500 Airplane Flight Manual Supplement No. GVII–G500 (Issue 1)–2020–05, dated September 8, 2020;

(ii) Gulfstream Aerospace GVII–G500 Airplane Flight Manual Supplement No. GVII–G500–2020–06, dated September 8, 2020; or

(iii) Gulfstream Aerospace GVII–G600 Airplane Flight Manual Supplement No. GVII–G600–2020–06, dated September 8, 2020.

(3) The action required by paragraph (g)(2) of this AD may be performed by the owner/ operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a)(1) through (4), and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Related Information

For more information about this AD, contact Jared Meyer, Aerospace Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5534; fax: (404) 474–5605; email: *jared.meyer@faa.gov.*

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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) Gulfstream Aerospace GVII–G500 Airplane Flight Manual Supplement No. GVII–G500 (Issue 1)–2020–05, dated September 8, 2020.

(ii) Gulfstream Aerospace GVII–G500 Airplane Flight Manual Supplement No. GVII–G500–2020–06, dated September 8, 2020.

(iii) Gulfstream Aerospace GVII–G600 Airplane Flight Manual Supplement No. GVII–G600–2020–06, dated September 8, 2020.

(iv) GVII–G500 Maintenance Manual 12–13–01 Defueling Procedure—Defuel, dated August 31, 2020.

Note 1 to paragraph (j)(2)(iv): Although the documents in paragraphs (j)(2)(iv) through (ix) have the watermarked words ''advance copy'' on each page of the document, these are not advance draft copies but final versions of temporary revisions to the AMM, pending incorporation into the AMM at the next revision.

(v) GVII–G500 Maintenance Manual 28–26–04 Fuel Boost Pump—Prime, dated August 31, 2020.

(vi) GVII–G600 Maintenance Manual 12–13–01 Defueling Procedure—Defuel, dated August 31, 2020.

(vii) GVII–G600 Maintenance Manual 28–26–04 Fuel Boost Pump—Prime, dated August 31, 2020.

(viii) GVII–G600 Maintenance Manual 28–26–04 Fuel Boost Pump—Removal/Installation dated August 31, 2020.

(ix) GVII–G600 Maintenance Manual 28–26–05 Fuel Boost Pump Canister—Removal/Installation, dated August 31, 2020.

(3) For Gulfstream Aerospace Corporation service information identified in this AD, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402; phone: (800) 810–4853; email: *pubs@gulfstream.com;* website: *https://www.gulfstream.com/en/customer-support/.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(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 go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 27, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–24808 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0378; Product Identifier 2018–SW–060–AD; Amendment 39–21316; AD 2020–22–20]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters. This AD requires visually inspecting each main rotor gearbox (MGB) suspension bar attachment bracket bolt for missing bolt heads. Depending on the outcome of the visual inspection, measuring the tightening torque, removing certain parts, sending photos and reporting information to Airbus Helicopters, and completing an FAA-approved repair is required. This AD was prompted by a report of a missing MGB suspension bar attachment bolt head. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD is effective December 14, 2020.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of December 14, 2020.

ADDRESSES: For service information identified in this final rule, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone 972–641–0000 or 800–232–0323; fax 972–641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0378.

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–2020–0378; 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 European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, any service information that is incorporated by reference, any comments received, and other information. The street 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: Kristi Bradley, Aerospace Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *kristin.bradley@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350C, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters. The NPRM published in the **Federal Register** on April 13, 2020, (85 FR 20447). The NPRM proposed to require visually inspecting each MGB suspension bar attachment bracket for missing bolt heads. If one bolt head is missing, the proposed AD would require performing actions specified in the service information including measuring the tightening torque of the remaining bolts of that bracket, removing the attachment bracket bolts, washers, and nuts of that bracket, and sending photos and reporting certain information to Airbus Helicopters. The proposed AD would also require repairs in accordance with an FAA-approved method if two or more bolt heads are missing. The proposed requirements were intended to prevent failure of the MGB suspension bar attachment bolts due to fatigue.

The NPRM was prompted by EASA AD No. 2018–0152, dated July 18, 2018 (EASA AD 2018–0152), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Airbus Helicopters (formerly Eurocopter, Eurocopter France) Model AS 350 B, AS 350 D, AS 350 B1, AS 350 B2, AS 350 BA, AS 350 BB, AS 350 B3, EC 130 B4, EC 130 T2, AS 355 E, AS355 F, AS355 F1, AS 355 F2, AS 355 N, and AS355 NP helicopters. EASA advises of a reported occurrence of a missing MGB suspension bar attachment bolt head.

EASA advises that investigations are ongoing to determine the root cause of this event. According to Airbus Helicopters, the missing MGB suspension bar attachment bolt head was discovered during scheduled maintenance of a Model EC 130 T2 helicopter. EASA states this condition could lead to fatigue failure of other affected bolts of the same MGB bracket, possibly resulting in loss of the MGB suspension bar and consequently loss of helicopter control. As an interim measure to address this potential unsafe condition, the EASA AD also includes Model AS 350 B, AS 350 D, AS 350 B1, AS 350 B2, AS 350 BA, AS 350 BB, AS 350 B3, EC 130 B4, AS 355 E, AS355 F, AS355 F1, AS355 F2, AS355 N, and AS355 NP helicopters in its applicability.

Accordingly, EASA AD 2018–0152 requires a one-time visual inspection to check that all MGB suspension bar attachment bracket bolt heads are present and depending on the outcome, measuring the tightening torque values of the bolts, removing and sending bolts, washers, and nuts to Airbus Helicopters, installing new bolts, washers, and nuts, sending photos and reporting certain information to Airbus Helicopters, and

contacting Airbus Helicopters for approved repair instructions. EASA states EASA AD 2018–0152 is considered an interim action and further AD action may follow.

Comments

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

Request

The commenter requested that this AD apply to Model AS350B3 and higher model helicopters, specifically Model AS350B3, AS350B3E, EC130B4, EC130T2, H125, and H130 helicopters. The commenter stated that, based on experience with a fleet of AS350BA and AS350B2 helicopters, the commenter has never seen a bolt head break on Model AS350BA and AS350B2 helicopters.

The FAA disagrees with removing models from the Applicability. The FAA determined that the unsafe condition exists and is likely to exist or develop on all the model helicopters included in the Applicability and is therefore requiring corrective action to address this unsafe condition on these models.

Request

The commenter requested the manufacturer add the inspection proposed in the NPRM to the 660-hour ''T'' inspection and also add the inspection after a certain number of flight hours after installation. The commenter gave an example of after 165 flying hours.

The FAA disagrees; the commenter provided no technical justification for changing the compliance times.

Actions Since Issuance of the NPRM

After the NPRM was issued, the FAA discovered that Airbus Helicopters Model AS350C was inadvertently included in the proposed Applicability. This helicopter model has a different engine model and therefore is not subject to the unsafe condition. The FAA has updated the Applicability section accordingly.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA of the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all information provided by EASA, reviewing the relevant information, considering the comments received, and determining the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed except for the change described previously. The FAA has determined that this change is consistent with the intent that was proposed for addressing the unsafe condition and does not add any additional burden upon the public than was already proposed in the NPRM except for minor editorial changes. These minor editorial changes are consistent with the intent of the proposals in the NPRM and will not increase the economic burden on any operator nor increase the scope of this AD.

Interim Action

The FAA considers this AD to be an interim action. If final action is later identified, the FAA might consider further rulemaking.

Differences Between This AD and the EASA AD

The EASA AD applies to Model AS350BB helicopters, whereas this AD does not because that model is not FAA type-certificated. The EASA AD directs the operators to contact Airbus Helicopters for repairs if more than one screw head is missing, whereas this AD does not.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Airbus Helicopter Alert Service Bulletin (ASB) No. AS350–05.00.92 for Model AS350B, B1, B2, B3, BA, and D helicopters, non-FAA type-certificated Model AS350BB helicopters, and military Model AS350L1 helicopters; Airbus Helicopters ASB No. AS355–05.00.79 for Model AS355E, F, F1, F2, N, and NP helicopters; and Airbus Helicopters ASB No. EC130–05A028 for Model EC130B4 and T2 helicopters, all Revision 0 and dated July 16, 2018. This service information specifies a one-time visual inspection using a light source and a mirror, and using an endoscope for any attachment bolts that are difficult to access, for the presence of the 16 attachment bracket bolt heads of the 4 MGB suspension bars. The service information also specifies different actions depending on the results of the visual inspection.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

The FAA also reviewed Airbus Standard Practices Manual (MTC) 20–02–05–404, Assembly by screws and nuts Joining, dated May 23, 2017. This service information specifies instructions for installing screws and nuts, tightening procedures when installing multiple bolts, tightening torque check and readjustment procedures, tooling information, measuring locking torque procedures, standard tightening torque procedures and values, torque tightening of screws in sandwich panels information, use of consumable materials and their correction coefficient values pertaining to screws, nuts, and washers, marking torque stripes, and re-installation criteria and inspection of attachment components.

Costs of Compliance

The FAA estimates that this AD affects 1,277 helicopters of U.S. Registry. The FAA estimates that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at $85 per work-hour.

Inspecting for any missing MGB suspension bar attachment bracket bolt heads takes about 2 work-hours for an estimated cost of $170 per helicopter and $217,090 for the U.S. fleet.

Measuring the tightening torque of three MGB suspension bar attachment bracket bolts and replacing the set of four MGB suspension bar attachment bracket bolts, washers, and nuts takes about 1 work-hour and parts cost about $50 for an estimated cost of $135 per helicopter.

Sending photos and reporting required information takes about 1 hour for an estimated cost of $85 per helicopter.

The FAA does not have the data to estimate the costs to do any FAA-approved repairs if two or more MGB suspension bar attachment bracket bolt heads are missing.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of

information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

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 helicopters identified in this rulemaking action.

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866,
2. Will not affect intrastate aviation in Alaska, and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2020–22–20 Airbus Helicopters: Amendment 39–21316; Docket No. FAA–2020–0378; Product Identifier 2018–SW–060–AD.

(a) Applicability

This AD applies to Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, AS355N, AS355NP, EC130B4, and EC130T2 helicopters, all serial numbers, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a missing main rotor gearbox (MGB) suspension bar attachment bracket bolt head. This condition could result in fatigue failure of the other MGB suspension bar attachment bracket bolts of the same MGB bracket, which could result in loss of the MGB suspension bar and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective December 14, 2020.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

For helicopters with less than 1035 hours time-in-service (TIS), before reaching 1200 hours TIS, and for helicopters with 1035 or more hours TIS, within 165 hours TIS or 12 months, whichever occurs first, visually inspect each MGB suspension bar attachment bracket bolt for missing bolt heads by following the Accomplishment Instructions, paragraph 3.B.2.a. of Airbus Helicopters Alert Service Bulletin (ASB) No. AS350–05.00.92, Airbus Helicopters ASB No. AS355–05.00.79, or Airbus Helicopters ASB No. EC130–05A028, all Revision 0 and dated July 16, 2018 (ASB AS350–05.00.92, ASB AS355–05.00.79, or ASB EC130–05A028), as applicable to your model helicopter. If any bolt heads are missing, do the following:

(1) If one bolt head is missing, do the actions under the section ''If only one screw head (a) is missing'' in the Accomplishment Instructions, paragraph 3.B.2.b of ASB AS350–05.00.92, ASB AS355–05.00.79, or ASB EC130–05A028, as applicable to your model helicopter, except you are not required to return removed parts to Airbus Helicopters. You must do the repair before further flight, and you must submit the photographs and reply form to Airbus Helicopters within 30 days of completing the inspection.

(2) If two or more bolt heads are missing, before further flight, repair using a method approved by the Manager, Rotorcraft Standards Branch. For a repair method to be approved by the Manager, Rotorcraft Standards Branch, as required by this paragraph, the Manager's approval letter must specifically refer to this AD.

Note 1 to paragraph (e): Airbus Helicopters refers to the bolts as screws.

(f) Special Flight Permits

Special Flight permits are prohibited.

(g) Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Kristi Bradley, Aerospace Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *kristin.bradley@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, the FAA suggests that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(i) Additional Information

(1) Airbus Standard Practices Manual (MTC) 20–02–05–404, Assembly by screws and nuts Joining, dated May 23, 2017, which is not incorporated by reference, contains additional information about the subject of

this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone 972–641–0000 or 800–232–0323; fax 972–641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.* You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD No. 2018–0152, dated July 18, 2018. You may view the EASA AD on the internet at *https://www.regulations.gov* in Docket No. FAA–2020–0378.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 6320, Main Rotor Gearbox.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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) Airbus Helicopters Alert Service Bulletin (ASB) No. AS350–05.00.92, Revision 0, dated July 16, 2018.

(ii) Airbus Helicopters ASB No. AS355–05.00.79, Revision 0, dated July 16, 2018.

(iii) Airbus Helicopters ASB No. EC130–05A028, Revision 0, dated July 16, 2018.

(3) For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone 972–641–0000 or 800–232–0323; fax 972–641–3775; or at *https://www.airbus.com/helicopters/services/technical-support.html.*

(4) You may view this service information 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.

(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 October 23, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–24675 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0464; Product Identifier 2020–NM–040–AD; Amendment 39–21307; AD 2020–22–11]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2017–18–17, which applied to all Airbus SAS Model A300 B4–603, A300 B4–620, A300 B4–622, A300 B4–605R, A300 B4–622R, A300 F4–605R, A300 F4–622R, and A300 C4–605R Variant F airplanes. AD 2017–18–17 required modifying certain fuselage frames and a repair on certain modified airplanes. This AD continues to require the actions in AD 2017–18–17, and also requires, for certain airplanes, an inspection to determine if rotating probe inspections were performed prior to oversizing of the open-holes, and repair if necessary; as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD was prompted by a report indicating that the material used to manufacture the upper frame feet was changed and negatively affected the fatigue life of the frame feet, and a determination that more work is required for certain airplanes that were previously modified. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 14, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 14, 2020.

ADDRESSES: For the material 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, 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–2020–0464.

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–2020–0464; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, 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: Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3225; email: *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0051, dated March 11, 2020 (''EASA AD 2020–0051'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A300 B4–603, A300 B4–620, A300 B4–622, A300 B4–605R, A300 B4–622R, A300 F4–605R, A300 F4–622R, A300 C4–620, and A300 C4–605R Variant F airplanes. Model A300 C4–620 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2017–18–17, Amendment 39–19026 (82 FR 43160, September 14, 2017) (''AD 2017–18–17''). AD 2017–18–17 applied to all Airbus SAS Model A300 B4–603, A300 B4–620, A300 B4–622, A300 B4–605R, A300 B4–622R, A300 F4–605R, A300 F4–622R, and A300 C4–605R Variant F airplanes. The NPRM published in the **Federal Register** on June 8, 2020 (85 FR 35016). The NPRM was prompted by a report indicating that the material used to manufacture the upper frame feet was changed and negatively affected the fatigue life of the frame feet, and a determination that more work is

required for certain airplanes that were previously modified. The NPRM proposed to continue to require the actions in AD 2017–18–17, as specified in an EASA AD. The NPRM also proposed to require, for certain airplanes, an inspection to determine if rotating probe inspections were performed prior to oversizing of the open-holes, and repair if necessary, as specified in an EASA AD.

The FAA is issuing this AD to address cracking of the center section of the fuselage, which could result in a ruptured frame foot and reduced structural integrity of the airplane. See the MCAI for additional background information.

Comments

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

Request for Credit for Using Previous Service Information

FedEx requested that the FAA provide credit for accomplishing the required actions using Airbus SAS Service Bulletin A300–53–6178, dated March 17, 2015, provided the appropriate rotating probe inspection is performed before oversizing the open holes. FedEx stated that its fleet is already in compliance with the required actions but used Airbus Service Bulletin A300–53–6178, dated March 17, 2015, not the current revision Airbus Service Bulletin A300–53–6178, Revision 01, dated September 20, 2019.

The FAA disagrees with the request. This AD incorporated by reference EASA AD 2020–0051 as the appropriate material to use to comply with this AD. Paragraph (3) of EASA AD 2020–0051 specifies that, for airplanes on which the modification specified in Airbus Service Bulletin A300–53–6178, dated March 17, 2015, was accomplished, additional work must be done. That additional work consists of determining whether or not a rotating probe inspection was performed before oversizing of the open-holes and, depending on findings, additional corrective actions. Therefore, the credit the commenter requested is already included in the requirements of this AD. The FAA has not revised this AD in this regard.

Conclusion

The FAA reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

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

Related IBR Material Under 1 CFR Part 51

EASA AD 2020–0051 describes procedures for modifying certain fuselage frames; a repair on certain modified airplanes; and, for certain airplanes, an inspection to determine if a rotating probe inspection was performed prior to oversizing of the open-holes, contacting the manufacturer for post-modification work instructions, and 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.

Costs of Compliance

The FAA estimates that this AD affects 65 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2017–18–17.	Up to 235 work-hours × $85 per hour = Up to $19,975.	$23,000	Up to $42,975	Up to $2,793,375.
New actions	1 work-hour × $85 per hour = $85	0	$85	$5,525

The FAA has received no definitive data that would enable providing cost estimates for the on-condition repairs specified in this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2017–18–17, Amendment 39–

19026 (82 FR 43160, September 14, 2017), and

■ b. Adding the following new AD:

2020–22–11 Airbus SAS: Amendment 39–21307; Docket No. FAA–2020–0464; Product Identifier 2020–NM–040–AD.

(a) Effective Date

This AD is effective December 14, 2020.

(b) Affected ADs

This AD replaces AD 2017–18–17, Amendment 39–19026 (82 FR 43160, September 14, 2017) (''AD 2017–18–17'').

(c) Applicability

This AD applies to all Airbus SAS Model A300 B4–603, A300 B4–620, A300 B4–622, A300 B4–605R, A300 B4–622R, A300 F4–605R, A300 F4–622R, and A300 C4–605R Variant F airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by a report indicating that the material used to manufacture the upper frame feet was changed and negatively affected the fatigue life of the frame feet, and a determination that more work is required for certain airplanes that were previously modified. The FAA is issuing this AD to address cracking of the center section of the fuselage, which could result in a ruptured frame foot and reduced structural integrity of 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, European Union Aviation Safety Agency (EASA) AD 2020–0051, dated March 11, 2020 (''EASA AD 2020–0051'').

(h) Exceptions to EASA AD 2020–0051

(1) Where EASA AD 2020–0051 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2020–0051 does not apply to this AD.

(3) For airplanes on which the modification specified in Airbus Service Bulletin A300–53–6178 has been done: Where paragraph (4) of EASA AD 2020–0051 specifies to do certain actions ''no later than 6 months (estimated by projection of airplane usage) prior to exceeding 24,500 flight cycles or 42,700 flight hours, whichever occurs first, after Airbus Service Bulletin A300–53–6178 embodiment (at any revision),'' this AD requires doing those actions prior to exceeding 24,100 total flight cycles or 42,000 total flight hours, whichever occurs first after doing the modification.

(i) 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 local Flight Standards District 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 (j) 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 local flight standards district office/certificate holding district 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 2020–0051 that contains RC procedures and tests: Except as required by paragraph (i)(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.

(j) Related Information

For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3225; email: *dan.rodina@faa.gov.*

(k) 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 this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2020–0051, dated March 11, 2020.

(ii) [Reserved]

(3) For EASA AD 2020–0051, 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.*

(4) 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–2020–0464.

(5) You may view this material 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 October 19, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–24641 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0451; Product Identifier 2020–NM–036–AD; Amendment 39–21302; AD 2020–22–06]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 99–01–19 and AD 2004–25–02, which applied to certain Airbus SAS Model A320 series airplanes. AD 99–01–19 and AD 2004–25–02 required repetitive inspections to detect fatigue cracking in certain areas of the fuselage, and corrective action if necessary. AD 2004–25–02 also provided an optional terminating action for the repetitive inspections. This AD continues to require, for certain airplanes, repetitive inspections of the fastener holes for any cracking, and repair if necessary, and provides an optional terminating action for the fastener hole inspections. This AD also revises the applicability to include additional airplanes and requires, for all airplanes, inspections of the emergency exit door structure for any cracking and repair if necessary; as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD was prompted by a report that during full scale tests to support the Model A320 structure extended service goal (ESG) exercise,

several cracks were found on both sides of the overwing emergency exit door cut-outs at fuselage section 15. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 14, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 14, 2020.

The Director of the Federal Register also approved the incorporation by reference of a certain other publication listed in this AD as of February 10, 2005 (70 FR 1184, January 6, 2005).

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of February 12, 1999 (64 FR 1114, January 8, 1999).

ADDRESSES: For EASA AD 2020–0040R1, which is incorporated by reference (IBR), 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.* For Airbus service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com*; internet *https://www.airbus.com.* You may view EASA AD 2020–0040R1 and the Airbus service information identified in this AD 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–2020–0451.

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–2020–0451; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, 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: Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *Sanjay.Ralhan@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0040R1, dated June 16, 2020 (''EASA AD 2020–0040R1'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; and Model A320–211, –212, –214, –215, –216, –231, –232, and –233 airplanes. Model A320–215 airplanes are not certified by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability. EASA AD 2020–0040R1 superseded French AD 2002–259(B), dated May 15, 2002 (which corresponded to FAA AD 2004–25–02, Amendment 39–13889 (70 FR 1184, January 6, 2005) (''AD 2004–25–02'')).

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 99–01–19, Amendment 39–10987 (64 FR 1114, January 8, 1999) (''AD 99–01–19''); and AD 2004–25–02. AD 99–01–19 and AD 2004–25–02 applied to certain Airbus SAS Model A320 series airplanes. The NPRM published in the **Federal Register** on June 4, 2020 (85 FR 34371). The NPRM was prompted by a report that during full scale tests to support the Model A320 structure ESG exercise, several cracks were found on both sides of the overwing emergency exit door cut-outs at fuselage section 15. The NPRM proposed to continue to require, for certain airplanes, repetitive inspections of the fastener holes for any cracking, and repair if necessary, and would provide an optional terminating action for the fastener hole inspections. The NPRM also proposed to revise the applicability to include additional airplanes and requires, for all airplanes, inspections of the emergency exit door structure for any cracking and repair if necessary, as specified in EASA AD 2020–0040R1.

The FAA is issuing this AD to address fatigue cracking of the fuselage, which could result in reduced structural integrity of the airplane. See the MCAI for additional background information.

Comments

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

Request To Use the Latest EASA AD

American Airlines (AAL) and United Airlines (UAL) requested that the NPRM specify EASA AD 2020–0040R1, which is the latest EASA AD, and it revises the applicability to exclude airplanes that have embodied certain modifications in production, and that those airplanes are, therefore, not applicable to the NPRM.

AAL stated that FAA AD 2004–25–02 and EASA AD 2020–0040R1 contain a difference in the applicability. AAL stated that FAA AD 2004–25–02 applies to Airbus Model A320 airplanes without modification 21346 embodied in production. AAL also stated that EASA AD 2020–0040R1 applies to all Airbus Model A319 and A320 airplanes, except for those with modification 160001 embodied in production, or Airbus Service Bulletin A320–57–1193 embodied in service, or Model A319 airplanes that have had modification 28238, 28162, and 28342 embodied in production. AAL commented that some of its Model A319 airplanes have had modification 160001 embodied in production, but would still be required to accomplish the actions specified in paragraph (k) of the NPRM.

The FAA agrees with the comment. The FAA has revised all applicable sections in this final rule to specify EASA AD 2020–0040R1, dated June 16, 2020, which clarifies the conditions and applicability for certain airplanes as of the effective date of this final rule. For clarification, airplane models that have embodied certain modifications or service information in production, paragraph (k) of this AD does not apply. The FAA has also determined that no additional work is required for airplanes on which the actions specified in EASA AD 2020–0040, dated February 28, 2020, have already been done.

Changes Since the NPRM Was Issued

The FAA inadvertently omitted paragraph (l)(4) from the proposed AD, and has added it to this AD to clarify that, ''The ''Remarks'' section of EASA AD 2020–0040R1 does not apply to this AD.''

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the change described

previously and minor editorial changes. The FAA has determined that these minor changes:

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

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

Related IBR Material Under 1 CFR Part 51

EASA AD 2020–0040R1 describes, among other actions, procedures for inspections of the emergency exit door structure for any cracking and repair, if necessary.

Airbus has issued Service Bulletin A320–53–1031, Revision 02, dated December 5, 2001. This service information describes procedures for repetitive rotating probe inspections of the fasteners holes and repair if necessary.

This AD also requires Airbus Service Bulletin A320–53–1032, Revision 02, dated December 5, 2001, which the Director of the Federal Register approved for incorporation by reference as of February 10, 2005 (70 FR 1184, January 6, 2005).

This AD also requires Airbus Service Bulletin A320–53–1032, Revision 01, dated January 15, 1998, which the Director of the Federal Register approved for incorporation by reference as of February 12, 1999 (64 FR 1114, January 8, 1999).

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.

Costs of Compliance

The FAA estimates that this AD affects 800 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2004–25–02.	Up to 19 work-hours × $85 per hour = Up to $1,615.	$0	Up to $1,615	Up to $1,292,000.
New actions	Up to 23 work-hours × $85 per hour = Up to $1,955.	0	Up to $1,955	Up to $1,564,000.

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: MODIFICATION, REPAIR OF FASTENER HOLES, AND REPAIR OF CRACKS IN THE EMERGENCY EXIT DOOR STRUCTURE THAT ARE WITHIN LIMITS

Labor cost	Parts cost	Cost per product
Up to 66 work-hours × $85 per hour = Up to $5,610	Up to $85,000	Up to $90,610.

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
1 work-hour × $85 per hour = $85	$4,219	$4,304

The FAA has received no definitive data that would enable the agency to provide cost estimates for certain other repairs specified in this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:
■ a. Removing Airworthiness Directive (AD) 99–01–19, Amendment 39–10987 (64 FR 1114, January 8, 1999); and AD 2004–25–02, Amendment 39–13889 (70 FR 1184, January 6, 2005); and
■ b. Adding the following new AD:

2020–22–06 Airbus SAS: Amendment 39–21302; Docket No. FAA–2020–0451; Product Identifier 2020–NM–036–AD.

(a) Effective Date

This AD is effective December 14, 2020.

(b) Affected ADs

This AD replaces AD 99–01–19, Amendment 39–10987 (64 FR 1114, January 8, 1999) (''AD 99–01–19''); and AD 2004–25–02, Amendment 39–13889 (70 FR 1184, January 6, 2005) (''AD 2004–25–02'').

(c) Applicability

This AD applies to Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; and Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2020–0040R1, dated June 16, 2020 (''EASA AD 2020–0040R1'').

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by a report that, during full scale tests to support the Model A320 structure extended service goal (ESG) exercise, several cracks were found on both sides of the overwing emergency exit door cut-outs at fuselage section 15. The FAA is issuing this AD to address fatigue cracking of the fuselage, which could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Initial Inspections, With No Changes

For Airbus SAS Model A320–111, –211, –212, and –231 series airplanes on which Airbus Modification 21346 has not been done: This paragraph restates the requirements of paragraph (f) of AD 2004–25–02, with no changes. At the applicable time specified in paragraph (g)(1) or (2) of this AD: Do a detailed inspection to find cracking on the outboard flanges around the fastener holes of frames 38 through 41, between stringers 12 and 21, using Airbus Service Bulletin A320–53–1032, Revision 02, dated December 5, 2001.

(1) For airplanes on which the inspection specified in Airbus Service Bulletin A320–53–1032, Revision 01, dated January 15, 1998; or Airbus Service Bulletin A320–53–1032, Revision 02, dated December 5, 2001; has been done as of February 10, 2005 (the effective date of AD 2004–25–02): Do the next inspection within 4,900 flight cycles after accomplishment of the last inspection, or within 1,100 flight cycles after February 10, 2005, whichever is later.

(2) For airplanes on which no inspection specified in Airbus Service Bulletin A320–53–1032, Revision 01, dated January 15, 1998; or Airbus Service Bulletin A320–53–1032, Revision 02, dated December 5, 2001; has been done as of February 10, 2005 (the effective date of AD 2004–25–02): Do the inspection at the earlier of the times specified in paragraphs (g)(2)(i) and (ii) of this AD.

(i) Before the accumulation of 30,000 total flight cycles.

(ii) Before the accumulation of 24,800 total flight cycles, or within 3,500 flight cycles after February 10, 2005 (the effective date of AD 2004–25–02), whichever is later.

(h) Retained Repetitive Inspections if No Cracking is Found, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2004–25–02, with no changes. If no crack is found during the inspection required by paragraph (g)(1) or (2) of this AD: Repeat the inspection thereafter at intervals not to exceed 4,900 flight cycles.

(i) Retained Corrective Actions With New Repetitive Inspections and Compliance Language

This paragraph restates the requirements of paragraph (h) of AD 2004–25–02, with new repetitive inspections and compliance language. If any crack is found during any inspection required by paragraph (g) of this AD, before further flight, repair using Airbus Service Bulletin A320–53–1032, Revision 01, dated January 15, 1998; or Airbus Service Bulletin A320–53–1032, Revision 02, dated December 5, 2001. Accomplishment of a repair using the service bulletin before the effective date of this AD ends the repetitive inspection requirements for the area repaired. As of the effective date of this AD, the repair does not constitute terminating action for the repetitive inspection. Thereafter, repeat the inspection at intervals not to exceed 4,900 flight cycles. If any crack is found during any inspection required by this AD, and the service bulletin specifies to contact Airbus for appropriate action: Before further flight, repair 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).

(j) Retained Optional Terminating Action With Changes to the Service Information Compliance Language

This paragraph restates the optional terminating action specified in paragraphs (i) and (j) of AD 2004–25–02, with changes to the service information compliance language. Accomplishment of Airbus Modification 21346 using Airbus Service Bulletin A320–53–1031, Revision 02, dated December 5, 2001, constitutes terminating action for the repetitive inspection requirements of paragraphs (h) and (i) this AD.

(k) New Requirements

Except as specified in paragraph (l) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2020–0040R1.

(l) Exceptions to EASA AD 2020–0040R1

(1) Where EASA AD 2020–0040R1 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2020–0040R1 refers to ''13 March 2020 [the effective date of the original issue of this AD],'' this AD requires using the effective date of this AD.

(3) Where EASA AD 2020–0040R1 requires the accomplishment of repetitive inspections and corrective actions as specified in paragraphs (1) and (2) of the EASA AD, those actions are not required by this AD as specified in the EASA AD. Those actions are required by paragraphs (g), (h), and (i) of this AD.

(4) The ''Remarks'' section of EASA AD 2020–0040R1 does not apply to this AD.

(m) Credit for Previous Actions

This paragraph provides credit for the optional terminating action specified in paragraph (j) of this AD, if Airbus Modification 21346 was performed before the effective date of this AD using Airbus Service Bulletin A320–53–1031, dated December 9, 1994.

(n) 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 local Flight Standards District 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 (o)(1) 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 local flight standards district office/certificate holding district 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 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

2020–0040R1 that contains RC procedures and tests: Except as required by paragraph (n)(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.

(o) Related Information

(1) Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *Sanjay.Ralhan@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (p)(6) and (7) of this AD.

(p) 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 this AD specifies otherwise.

(3) The following service information was approved for IBR on December 14, 2020.

(i) European Union Aviation Safety Agency (EASA) AD 2020–0040R1, dated June 16, 2020.

(ii) Airbus Service Bulletin A320–53–1031, Revision 02, dated December 5, 2001.

(4) The following service information was approved for IBR on February 10, 2005 (70 FR 1184, January 6, 2005).

(i) Airbus Service Bulletin A320–53–1032, Revision 02, dated December 5, 2001.

(ii) [Reserved]

(5) The following service information was also approved for IBR on February 12, 1999 (64 FR 1114, January 8, 1999).

(i) Airbus Service Bulletin A320–53–1032, Revision 01, dated January 15, 1998.

(ii) [Reserved]

(6) For EASA AD 2020–0040R1, 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.* For Airbus material, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com*; internet *https://www.airbus.com.*

(7) 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–2020–0451.

(8) You may view this material 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 October 15, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–24642 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0719; Project Identifier 2019–CE–041–AD; Amendment 39–21313; AD 2020–22–17]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Pilatus Aircraft Ltd. (Pilatus) Model PC–24 airplanes. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as movement of the aft fuel pipe within the coupling, which can cause damage to the O-rings and lead to a fuel leak, fuel fire or explosion, and consequent loss of control of the airplane. This AD requires replacing and prohibits installing affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 14, 2020.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 14, 2020.

ADDRESSES: For service information identified in this final rule, contact Pilatus Aircraft Ltd., Customer Support General Aviation, CH–6371 Stans, Switzerland, telephone: +41 848 24 7 365, *techsupport.ch@pilatus-aircraft.com, https://www.pilatus-aircraft.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call 816–329–4148. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0719.

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–2020–0719; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the 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: Doug Rudolph, Aerospace Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Pilatus Model PC–24 airplanes with a certain part-numbered flexible saddle clamp installed between frame 34 and 36. The NPRM published in the **Federal Register** on July 30, 2020 (85 FR 45810). The NPRM proposed to require actions to correct the unsafe condition on the specified products and was prompted by MCAI originated by the European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. EASA issued AD No. 2019–0240, dated September 25, 2019 (referred to after this as ''the MCAI''), which states:

> An occurrence was reported where, during maintenance, when system pressure was applied to a motive-flow fuel pipe, the aft fuel pipe was found to move to the end stop within the coupling. When system pressure was released, the aft fuel pipe returned to its point of origin. This movement can cause damage to the O-rings.
>
> This condition, if not corrected, could lead to a fuel leak and consequently a fuel contamination of the rear fuselage, which, in combination with an ignition source in this

area, could possibly result in a fuel fire or fuel vapour explosion and consequent loss of the aeroplane.

To address this potential unsafe condition, Pilatus issued the [service bulletin] SB to provide modification instructions.

For the reason described above, this [EASA] AD requires replacement of affected parts with serviceable parts, as defined in this AD, and prohibits (re-) installation of affected parts.

You may examine the MCAI on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0719.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Pilatus PC–24 Service Bulletin No. 28–002, dated May 3, 2019. The service information contains procedures for replacing the two flexible saddle clamps on the left-hand (LH) motive-flow fuel pipe and the two flexible saddle clamps on the right-hand (RH) motive-flow fuel pipe with fixed saddle clamps. This service information also contains procedures for replacing the four O-rings on the LH and RH motive-flow fuel pipes. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD will affect 16 products of U.S. registry. The FAA also estimates that it will take about 7 work-hours per product to comply with the requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $5,000 per product.

Based on these figures, the FAA estimates the cost of the AD on U.S. operators will be $89,520 or $5,595 per product.

According to the manufacturer, all or some of the costs of this 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 costs in this 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

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 this AD:

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2020–22–17 Pilatus Aircraft Ltd.: Amendment 39–21313; Docket No. FAA–2020–0719; Project Identifier 2019–CE–041–AD.

(a) Effective Date

This airworthiness directive (AD) is effective December 14, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pilatus Aircraft Ltd. Model PC–24 airplanes, all serial numbers, certificated in any category, with a flexible saddle clamp part number (P/N) 946.33.22.004 installed between frame 34 and 36.

(d) Subject

Joint Aircraft System Component (JASC) Code 2800: Fuel.

(e) Reason

This AD was prompted by an occurrence of movement of the aft fuel pipe within the coupling when system pressure was applied. This movement can cause damage to the O-rings, which could lead to a fuel leak and fuel contamination of the rear fuselage. The FAA is issuing this AD to prevent a fuel fire or fuel vapor explosion with consequent loss of airplane control.

(f) Actions and Compliance

Unless already done, do the following actions in accordance with the applicable compliance times:

(1) Within 3 months after the effective date of this AD, replace each flexible saddle clamp with a fixed saddle clamp with P/N 946.33.21.933, align the left-hand (LH) and right-hand (RH) motive-flow fuel pipes, and test the LH and RH motive-flow fuel pipe for leaks in accordance with the Accomplishment Instructions, sections 3.B and 3.C, of Pilatus PC–24 Service Bulletin No. 28–002, dated May 3, 2019.

(2) As of the effective date of this AD, do not install a flexible saddle clamp with P/N 946.33.22.004 between frame 34 and 36 on any airplane.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to Doug Rudolph, Aerospace Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(h) Related Information

Refer to European Union Aviation Safety Agency (EASA) AD No. 2019–0240, dated September 25, 2019, for more information. You may examine the EASA AD in the AD

docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0719.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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) Pilatus PC–24 Service Bulletin No. 28–002, dated May 3, 2019.

(ii) [Reserved]

(3) For Pilatus Aircraft Ltd. service information identified in this AD, contact Pilatus Aircraft Ltd., Customer Technical Support (MCC), P.O. Box 992, CH–6371 Stans, Switzerland; telephone: +41 (0)41 619 67 74; fax: +41 (0)41 619 67 73; email: *techsupport@pilatus-aircraft.com;* internet: *https://www.pilatus-aircraft.com/en.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri. For information on the availability of this material at the FAA, call 816–329–4148.

(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 October 22, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–24805 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 23

RIN 3038–AF03

Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is adopting amendments to the margin requirements for uncleared swaps for swap dealers (''SD'') and major swap participants (''MSP'') for which there is not a prudential regulator (the ''CFTC Margin Rule''). Specifically, the CFTC Margin Rule mandated the collection and posting of variation margin and initial margin (''IM'') under a phased compliance schedule extending from September 1, 2016, to September 1, 2020. The Commission is hereby amending the compliance schedule to further delay the compliance date for entities with smaller average daily aggregate notional amounts (''AANA'') of swaps and certain other financial products (the ''Smaller Portfolio Group'') from September 1, 2021, to September 1, 2022, to avoid market disruption due to the large number of entities being required to comply by September 1, 2021, as a result of the adoption of the interim final rule (''Final Rule'').

DATES: This final rule is effective December 9, 2020.

FOR FURTHER INFORMATION CONTACT: Joshua B. Sterling, Director, 202–418–6056, *jsterling@cftc.gov;* Thomas J. Smith, Deputy Director, 202–418–5495, *tsmith@cftc.gov;* Warren Gorlick, Associate Director, 202–418–5195, *wgorlick@cftc.gov;* or Carmen Moncada-Terry, Special Counsel, 202–418–5795, *cmoncada-terry@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

Section 4s(e) of the Commodity Exchange Act (''CEA'') [1] requires the Commission to adopt rules establishing minimum initial and variation margin requirements for all swaps [2] that are (i) entered into by an SD or MSP for which there is not a prudential regulator [3] (collectively, ''covered swap entities'' or ''CSEs'') and (ii) not cleared by a registered derivatives clearing organization (''uncleared swaps'').[4] To offset the greater risk to the SD [5] or MSP [6] and the financial system arising from the use of uncleared swaps, these requirements must (i) help ensure the safety and soundness of the SD or MSP and (ii) be appropriate for the risk associated with the uncleared swaps held by the SD or MSP.[7]

The Basel Committee on Banking Supervision and the International Organization of Securities Commissions (''BCBS/IOSCO'') established an international framework for margin requirements for uncleared derivatives in September 2013 (the ''BCBS/IOSCO Framework'').[8] After the establishment of the BCBS/IOSCO Framework, on January 6, 2016, the CFTC, consistent with Section 4s(e), promulgated rules requiring CSEs to collect and post initial and variation margin for uncleared swaps,[9] adopting the implementation schedule set forth in the BCBS/IOSCO Framework, including the revised implementation schedule adopted on March 18, 2015.[10]

In July 2019, BCBS/IOSCO further revised the framework to extend the implementation schedule to September 1, 2021.[11] Consistent with this revision to the international framework, the Commission promulgated the April 2020 Final Rule,[12] which amended the

[1] 7 U.S.C. 6s(e) (capital and margin requirements).

[2] CEA section 1a(47), 7 U.S.C. 1a(47) (swap definition); Commission regulation 1.3, 17 CFR 1.3 (further definition of a swap). A swap includes, among other things, an interest rate swap, commodity swap, credit default swap, and currency swap.

[3] CEA section 1a(39), 7 U.S.C. 1a(39) (defining the term ''prudential regulator'' to include the Board of Governors of the Federal Reserve System; the Office of the Comptroller of the Currency; the Federal Deposit Insurance Corporation; the Farm Credit Administration; and the Federal Housing Finance Agency). The definition of prudential regulator further specifies the entities for which these agencies act as prudential regulators. The prudential regulators published final margin requirements in November 2015. *See generally* Margin and Capital Requirements for Covered Swap Entities, 80 FR 74840 (Nov. 30, 2015) (''Prudential Margin Rule''). The Prudential Margin Rule is similar to the CFTC Margin Rule, including with respect to the CFTC's phasing-in of margin requirements, as discussed below.

[4] CEA section 4s(e)(2)(B)(ii), 7 U.S.C. 6s(e)(2)(B)(ii). In Commission regulation 23.151, the Commission further defined the term uncleared swap to mean a swap that is not cleared by a registered derivatives clearing organization or by a derivatives clearing organization that the Commission has exempted from registration as provided under the CEA. 17 CFR 23.151.

[5] CEA section 1a(49), 7 U.S.C. 1a(49) (swap dealer definition); Commission regulation 1.3 (further definition of swap dealer).

[6] CEA section 1a(32), 7 U.S.C. 1a(32) (major swap participant definition); Commission regulation 1.3 (further definition of major swap participant).

[7] CEA section 4s(e)(3)(A), 7 U.S.C. 6s(e)(3)(A).

[8] *See generally* BCBS and IOSCO, Margin requirements for non-centrally cleared derivatives (Sept. 2013), *https://www.bis.org/publ/bcbs261.pdf.*

[9] *See generally* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 81 FR 636 (Jan. 6, 2016). The CFTC Margin Rule, which became effective April 1, 2016, is codified in part 23 of the Commission's regulations. 17 CFR 23.150–23.159, 23.161. In May 2016, the Commission amended the CFTC Margin Rule to add Commission regulation 23.160, 17 CFR 23.160, providing rules on its cross-border application. *See generally* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants—Cross-Border Application of the Margin Requirements, 81 FR 34818 (May 31, 2016).

[10] *See generally* BCBS/IOSCO, Margin requirements for non-centrally cleared derivatives (March 2015), *https://www.bis.org/bcbs/publ/d317.pdf.*

[11] *See generally* BCBS/IOSCO, Margin requirements for non-centrally cleared derivatives (July 2019), *https://www.bis.org/bcbs/publ/d475.pdf* (''2019 BCBS/IOSCO Margin Framework'').

[12] On April 9, 2020, the Commission published in the **Federal Register** a final rule extending the September 1, 2020 compliance date by one year to September 1, 2021, for the Smaller Portfolio Group, which were required to comply with IM requirements in the last phase of compliance, to

compliance schedule for the IM requirements under the CFTC Margin Rule by splitting the last phase of compliance into two compliance phases beginning on September 1, 2020, and September 1, 2021, respectively.[13]

The World Health Organization declared the coronavirus disease 2019 (''COVID–19'') outbreak a global pandemic on March 11, 2020.[14] On March 13, 2020, President Donald J. Trump declared a national emergency due to the COVID–19 pandemic.[15] The disease has impacted individuals across the world and severely disrupted domestic and international business, and adversely impacted the global economy.

In response to significant concerns regarding the COVID–19 outbreak, BCBS/IOSCO decided to amend its margin policy framework to further extend the implementation schedule for the margin requirements for non-centrally cleared derivatives by one year.[16] BCBS/IOSCO, in a joint statement, stated that the extension would provide additional operational capacity for firms to respond to the immediate impact of COVID–19 and at the same time facilitate firms' diligent efforts to comply with the requirements by the revised deadlines.[17]

After taking into consideration the revised BCBS/IOSCO implementation schedule, in May 2020, the Commission amended the IM compliance schedule for certain entities by one year (''IFR Extension Group''), which otherwise would have been required to comply with the IM requirements beginning on September 1, 2020, to extend the compliance date to September 1, 2021.[18] The Commission accomplished this change by means of an interim final rule (''IFR'') [19] in order to address the immediate impact of the COVID–19 pandemic on the IFR Extension Group in an expedited and timely manner; however, the Commission did not extend the compliance date for the Smaller Portfolio Group, which is still September 1, 2021, the same day as the revised IFR Extension Group compliance date.

As a result of the IFR, the IFR Extension Group and the Smaller Portfolio Group are effectively consolidated into one phase and will be required to begin compliance at the same time on September 1, 2021. The IFR Extension Group and the Smaller Portfolio Group will face the same issues that the April 2020 Final Rule intended to address, including the limited number of entities that provide IM required services. In recognition of this concern, the Commission, after adopting the IFR extending the IFR Extension Group compliance date to September 1, 2021, approved a notice of proposed rulemaking to amend and extend the IM compliance schedule for the Smaller Portfolio Group to September 1, 2022 (''Proposal'').[20]

II. Final Rule

The Commission is adopting the Final Rule to amend the CFTC Margin Rule to extend the compliance schedule for the IM requirements for the Smaller Portfolio Group. As a result of this rule amendment, the compliance date of September 1, 2021, applicable to the Smaller Portfolio Group, will be delayed by one year, and entities in this group will now be required to comply with the IM requirements in a final sixth phase beginning on September 1, 2022. As stated in the Proposal, the extension of the schedule for compliance with the IM requirements is consistent with the 2020 BCBS/IOSCO Margin Framework and similar action undertaken by the U.S. prudential regulators and the Commission's international counterparts.[21]

The Commission received one comment letter expressing support for the Proposal to extend the CFTC compliance schedule for the Smaller Portfolio Group. [22] This comment letter, which was a joint industry letter submitted by eleven trade associations, stated that deferral of the Smaller Portfolio Group compliance date is necessary to facilitate orderly preparation for the exchange of regulatory IM between CSEs and covered counterparties expected to come into the scope of the IM

reduce the potential market disruption that could result from the large number of entities that would come into the scope of compliance on September 1, 2020, absent the amendment of the compliance schedule (''April 2020 Final Rule'').

[13] *See generally* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 85 FR 19878 (April 9, 2020).

[14] WHO Director-General's opening remarks at the media briefing on COVID–19 (March 11, 2020), *https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.*

[15] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (March 13, 2020), *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

[16] *See generally* BCBS/IOSCO, Margin requirements for non-centrally cleared derivatives (April 2020), *https://www.bis.org/bcbs/publ/d499.htm* (''2020 BCBS/IOSCO Margin Framework'') and Press Release, April 3, 2020, *https://www.bis.org/press/p200403a.htm* (''April 2020 BCBS/IOSCO Press Release'').

[17] Basel Committee and IOSCO announce deferral of final implementation phases of the margin requirements for non-centrally cleared derivatives (April 3, 2020), *https://www.bis.org/press/p200403a.htm.*

[18] *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 85 FR 41346 (July 10, 2020). A Global Markets Advisory Committee (''GMAC'') subcommittee also encouraged the adoption of the BCBS/IOSCO recommendation to extend the implementation schedule given the circumstances brought about by the COVID–19 pandemic. *See* Recommendations to Improve Scoping and Implementation of Initial Margin Requirements for Non-Cleared Swaps, Report to the CFTC's Global Markets Advisory Committee by the Subcommittee on Margin Requirements for Non-Cleared Swaps, at 3 (May 2020), *https://www.cftc.gov/media/3886/GMAC_051920MarginSubcommitteeReport/download.* The GMAC adopted the subcommittee's report and recommended to the Commission that it consider adopting the report's recommendations. The GMAC subcommittee was not tasked to respond to the COVID–19 pandemic. Rather, its establishment pre-dates the pandemic's impact, and its directive was to address the ongoing challenges involving the implementation of the CFTC margin requirements during the last stages of the compliance schedule. *See* CFTC Commissioner Stump Announces New GMAC Subcommittee on Margin Requirements for Non-Cleared Swaps (Oct. 28, 2019), *https://www.cftc.gov/PressRoom/PressReleases/8064-19.*

[19] Subsequently, on July 10, 2020, to mitigate the operational challenges faced by certain entities subject to the CFTC Margin Rule as a result of the COVID–19 pandemic, the Commission published in the **Federal Register** an interim final rule extending the September 1, 2020 compliance date for the IFR Extension Group to September 1, 2021.

[20] *See* Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 85 FR 41463 (July 10, 2020).

[21] The U.S. prudential regulators (*i.e.,* the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of the Comptroller of the Currency) recently issued an interim final rule to revise their margin compliance schedule consistent with the revised BCBS/IOSCO implementation schedule. *See* Margin and Capital Requirements for Covered Swap Entities, 85 FR 39464 (July 1, 2020). In addition, the European Securities and Markets Authority (ESMA), the European Banking Authority (EBA) and the European Insurance and Occupational Pensions Authority (EIOPA), collectively known as the European Supervisory Authorities (ESAs), submitted, for endorsement by the European Commission, joint draft Regulatory Technical Standards (RTS) proposing changes to the European Union margin rules to effectively implement the 2020 BCBS/IOSCO Margin Framework's implementation schedule revisions. *See* Final Report, EMIR RTS on Various Amendments to the Bilateral Margin Requirements in View of the International Framework (May 4, 2020), *https://www.esma.europa.eu/sites/default/files/library/esas_2020_09_-_final_report_-_bilateral_margin_amendments.pdf.*

[22] Comment letter no. 62694 from the International Swaps and Derivatives Association, the Securities Industry and Financial Markets Association, SIFMA Asset Management Group, the Global Financial Markets Association, the Global Foreign Exchange Division of GFMA, Managed Funds Association, Investment Adviser Association, the Institute of International Bankers, the Investment Company Institute, the U.S. Chamber's Center for Capital Markets Competitiveness (CCMC) and the American Council of Life Insurers (Aug. 5, 2020), *https://comments.cftc.gov/Handlers/PdfHandler.ashx?id=29412.*

requirements in the last phases of compliance. The comment letter went on to note that given the disruptive nature of the pandemic, notwithstanding robust business continuity plans, efforts to prepare for the final phases of regulatory IM have been disrupted due to personnel, systems, and other issues, and, therefore, the commenters appreciate the additional time afforded to market participants in the Proposal.

Covered swap entities are required to post and collect IM with counterparties that are SDs, MSPs, or financial end users with material swap exposure (''MSE'')[23] (''covered counterparties'') in accordance with a phased compliance schedule set forth in Commission regulation 23.161.[24] The compliance schedule, which originally extended from September 1, 2016 to September 1, 2020, and comprised five phases, brings into compliance with the IM requirements CSEs and covered counterparties on staggered dates, starting with entities with the largest AANA of uncleared swaps and certain other financial products, and then progressively with successively lesser AANA.

The April 2020 Final Rule split the fifth and last phase of compliance into two phases, extending the compliance date for the Smaller Portfolio Group to September 1, 2021. Subsequently, the IFR extended the IFR Extension Group's September 1, 2020 compliance date to September 1, 2021, and as a result, the IFR Extension Group and Smaller Portfolio Group would be required to begin IM compliance on the same day absent the Commission's adoption of this Final Rule.

Absent the Commission's adoption of the Proposal in this Final Rule, the onset of the compliance phase starting on September 1, 2021, would result in a very large number of entities coming into compliance simultaneously, because the AANA threshold for compliance with the IM requirements would be significantly reduced. Specifically, entities in the fourth phase were subject to a $750 billion AANA threshold, and beginning on September 1, 2021, under the schedule being revised by the Final Rule, entities will come within the scope of IM compliance if their AANA exceeds $8 billion. According to the CFTC's Office of the Chief Economist (''OCE''), compared with the first through fourth phase of compliance, which brought fewer than 40 entities into scope, the two groups now subject to the September 1, 2021 compliance date will bring into scope approximately 670 entities, along with 7,500 swap trading relationships.[25] This means that approximately 670 entities may have to amend or enter into up to 7,500 new sets of credit support or other IM agreements in order to continue to engage in swap transactions.

The Commission adopted the April 2020 Final Rule, which postponed the compliance date for the Smaller Portfolio Group, to address concerns that the large number of counterparties preparing to meet the September 1, 2020 deadline would seek to engage the same limited number of entities that provide IM required services, involving, among other things, the preparation of IM-related documentation, the approval and implementation of risk-based models for IM calculation, and in some cases the establishment of custodial arrangements. In the preamble to the April 2020 Final Rule, the Commission stated that compliance delays could lead to disruption in the markets; for example, some counterparties could, for a time, be restricted from entering into uncleared swaps and therefore might be unable to use swaps to hedge their financial risk.

Because the IFR moved the compliance date for the IFR Extension Group to the same date as the Smaller Portfolio Group in response to the COVID–19 pandemic, both groups would face, absent the Commission's adoption of this Final Rule, effectively the same issues that the April 2020 Final Rule intended to address, including the limited number of entities that provide IM-required services. The Commission is adopting the Final Rule to further delay the compliance date for the Smaller Portfolio Group entities to alleviate the potential market disruption described above, consistent with the rationale for the Commission's adoption of the April 2020 Final Rule.

The Final Rule will align the CFTC Margin Rule with the 2020 BCBS/IOSCO Margin Framework and is in line with similar efforts by the U.S. prudential regulators and international counterparts.[26] The Final Rule will thus advance the Commission's goal of achieving regulatory harmonization with respect to uncleared swaps margin and may help reduce regulatory arbitrage.

The Commission notes that the Smaller Portfolio Group comprises entities with a relatively small amount of swap activity. The OCE estimates that the average AANA per entity subject to the original September 1, 2020 compliance date is about $59 billion, compared to an average $10.6 trillion AANA for each entity in the earlier phases 1, 2, and 3 and $1 trillion in phase 4. OCE also estimates that the total AANA for the Smaller Portfolio Group would be approximately four percent of the total AANA across all the phases.[27] Given the relatively small amount of swap activity of entities in the Smaller Portfolio Group, the Commission believes that delaying compliance with the IM requirements by one year for such group will have a muted impact on the systemic risk mitigating effects of the IM requirements. In addition, the Commission notes that the potential for systemic risk also is reduced because the Final Rule does not relieve Smaller Portfolio Group firms from their existing obligations to cover their current exposure on a daily basis through mandated variation margin payments once such firms have reached the minimum transfer amount, as this term is defined in the Commission's rules.[28]

Although the impact of Smaller Portfolio Group swap activity on systemic risk is likely to be muted during the one year delay, the Commission notes that the time limited risk for the additional year should not be interpreted as dismissive of the longer term regulatory implications of this swap activity. The Commission believes that the exchange of IM by entities with relatively small portfolios

[23] Commission regulation 23.151 provides that MSE for an entity means that the entity and its margin affiliates have an average daily aggregate notional amount of uncleared swaps, uncleared security-based swaps, foreign exchange forwards, and foreign exchange swaps with all counterparties for June, July or August of the previous calendar year that exceeds $8 billion, where such amount is calculated only for business days. A company is a ''margin affiliate'' of another company if: (i) Either company consolidates the other on a financial statement prepared in accordance with U.S. Generally Accepted Accounting Principles, the International Financial Reporting Standards, or other similar standards; (ii) both companies are consolidated with a third company on a financial statement prepared in accordance with such principles or standards; or (iii) for a company that is not subject to such principles or standards, if consolidation as described in paragraph (1) or (2) of this definition would have occurred if such principles or standards had applied. 17 CFR 23.151.

[24] 17 CFR 23.161.

[25] Richard Haynes, Madison Lau, & Bruce Tuckman, *Initial Margin Phase 5,* at 4–7 (Oct. 24, 2018), *https://www.cftc.gov/sites/default/files/About/Economic%20Analysis/Initial%20Margin%20Phase%205%20v5_ada.pdf* (''OCE Initial Margin Phase 5 Study''). The OCE Study defines ''a 'relationship' as an entity and a swap dealer, where the entity is an aggregation of related affiliates.''

[26] *See* supra note 19.

[27] The methodology for calculating AANA is described in the OCE Initial Margin Phase 5 Study at 3.

[28] 17 CFR 23.151.

supports the health and stability of the overall financial system.

III. Related Matters

A. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'')[29] imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined by the PRA. The Commission may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number. This Final Rule, as adopted, contains no requirements subject to the PRA.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'') requires that agencies, in promulgating regulations, consider whether the regulations they propose will have a significant economic impact on a substantial number of small entities, and, if so, to provide a flexibility analysis regarding the economic impact on those entities.[30] In the Proposal, the Commission certified that it would not have a significant economic impact on a substantial number of small entities. The Commission requested comments with respect to the RFA and received no comments.

As discussed in the Proposal, the Final Rule only affects SDs and MSPs that are subject to the CFTC Margin Rule and their covered counterparties, all of which are required to be eligible contract participants (''ECPs'').[31] The Commission has previously determined that SDs, MSPs, and ECPs are not small entities for purposes of the RFA.[32] Therefore, the Commission believes that this Final Rule will not have a significant economic impact on a substantial number of small entities, as defined in the RFA.

Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that this Final Rule will not have a significant economic impact on a substantial number of small entities.

C. Cost-Benefit Considerations

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of the following five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) considerations. Further, the Commission has considered the extraterritorial reach of the Final Rule and notes where this reach may be especially relevant.

This Final Rule extends the compliance schedule for the CFTC Margin Rule for CSEs and covered counterparties in the Smaller Portfolio Group, including financial end user counterparties exceeding the MSE threshold of $8 billion in AANA. As a result of the Commission's adoption of this Final Rule, these entities will come into scope in a final sixth phase, which will begin on September 1, 2022.

As discussed above, the Commission believes that with the earlier adoption of the IFR and the resulting reapplication of the same compliance deadline for both the Smaller Portfolio Group and the IFR Extension Group, the resulting large number of counterparties that would have been required to comply with the IM requirements for the first time on September 1, 2021, absent the Final Rule, could have caused certain market disruptions. Some CSEs and covered counterparties would have been strained given the demand for resources and services to meet the September 2021 deadline and operationalize the exchange of IM, involving, among other things, counterparty onboarding, approval and implementation of risk-based models for the calculation of IM, and documentation associated with the exchange of IM.

The baseline against which the benefits and costs associated with this Final Rule are compared is the uncleared swaps markets as they exist today, including the impact of the compliance schedule being amended herein, which would have required IM compliance by September 1, 2021. With this as the baseline, the following are the benefits and costs of this Final Rule.

The Commission sought comment on all aspects of the cost and benefit considerations in the Proposal but received no substantive comments.

1. Benefits

As described above, this Final Rule extends the compliance schedule for the IM requirements for the Smaller Portfolio Group to September 1, 2022. The extension benefits entities in the Smaller Portfolio Group by allowing them to trade uncleared swaps more easily and cheaply over this period. It also benefits entities in the IFR Extension Group by making it easier for them to obtain the resources needed to comply with the IM requirements. This Final Rule is specifically intended to alleviate the potential market disruption resulting from the large number of counterparties that would have come into scope on September 1, 2021, under the compliance schedule being amended, and the strain on the uncleared swaps markets resulting from the increased demand for limited resources and services to set up operations to comply with the IM requirements, including counterparty onboarding, adoption and implementation of risk-based models to calculate IM, and documentation associated with the exchange of IM. In contrast with the CFTC's existing requirements mandating that the entities in the Smaller Portfolio Group comply with the IM requirements at the same time as entities in the IFR Extension Group, the Final Rule reduces the potential for bottlenecks by creating a one-year separation in the applicable compliance dates for the two categories of entities.

The Final Rule provides a 12-month delay for smaller counterparties that comprise the Smaller Portfolio Group to September 1, 2022, whose swap trading may not pose the same level of risk as entities in the IFR Extension Group, to prepare for their compliance with the IM requirements. The Final Rule therefore promotes the smooth and orderly transition into IM compliance for both the IFR Extension Group and the Smaller Portfolio Group.

The Final Rule amends the CFTC Margin Rule consistent with the 2020 BCBS/IOSCO Margin Framework and the prudential regulators' June 2020 IFR amending the IM compliance schedule. The Final Rule therefore promotes harmonization with international and domestic margin regulatory requirements, thereby reducing the potential for regulatory arbitrage.

[29] 44 U.S.C. 3501 *et seq.*

[30] 5 U.S.C. 601 *et seq.*

[31] Each counterparty to an uncleared swap must be an ECP, as the term is defined in section 1a(18) of the CEA, 7 U.S.C. 1a(18) and Commission regulation 1.3, 17 CFR 1.3. *See* 7 U.S.C. 2(e).

[32] *See* Registration of Swap Dealers and Major Swap Participants, 77 FR 2613, 2620 (Jan. 19, 2012) (SDs and MSPs) and Opting Out of Segregation, 66 FR 20740, 20743 (April 25, 2001) (ECPs).

2. Costs

The Final Rule extends the time frame for compliance with the IM requirements for the smallest, in terms of notional amount, CSEs and covered counterparties, including SDs and MSPs and financial end users that exceed an MSE of $8 billion, by an additional 12 months. Uncleared swaps entered into during this period with the smallest CSEs may be treated as legacy swaps not subject to the IM requirements. As IM might not be required to be collected on some of these swaps,[33] the one-year compliance delay may increase the level of counterparty credit risk to the financial system. While potentially meaningful, in the Commission's view this risk is a relatively lesser concern because these legacy swap portfolios would be entered into with counterparties that engage in lower levels of notional trading.

3. Section 15(a) Considerations

In light of the foregoing, the CFTC has evaluated the costs and benefits of this Final Rule pursuant to the five considerations identified in section 15(a) of the CEA as follows:

(a) Protection of Market Participants and the Public

This Final Rule will protect market participants and the public against the potential disruption that may have been caused by the large number of counterparties that would have come into the scope of the IM requirements on September 1, 2021, under the compliance schedule being amended by this Final Rule.

Under the revised compliance schedule set forth in the Final Rule, fewer counterparties will come into scope by September 1, 2021, and many small counterparties will be able to defer compliance until the last compliance date on September 1, 2022. As such, the demand for resources and services to achieve operational readiness will be reduced, mitigating the potential strain on the uncleared swaps markets.

Inasmuch as this Final Rule delays the implementation of IM for the smallest CSEs, there may not be as much IM posted to protect the financial system as would otherwise be the case.

(b) Efficiency, Competitiveness, and Financial Integrity of Markets

The Final Rule is expected to make the uncleared swaps markets more efficient by facilitating counterparties' transition into compliance with the IM requirements, thus avoiding inefficiencies in the documentation and implementation process. Counterparties will have additional time to document their swap relationships and set up adequate processes to operationalize the exchange of IM. As such, the Final Rule could promote more even competition among counterparties in the uncleared swaps markets, as the one-year delay period may remove the potential incentive for CSEs to prioritize arrangements with larger counterparties to the detriment of smaller counterparties and may thus help maintain the current state of market efficiency.

By preventing the market disruption that would have resulted from the large number of counterparties that would have come into scope by September 1, 2021, and the use of finite financial infrastructure resources, the Final Rule promotes the financial integrity of the markets. On the other hand, for a one-year period, there will be less IM posted overall, making uncleared swaps markets more susceptible to financial contagion where the default of one counterparty could lead to subsequent defaults of other counterparties, potentially harming market integrity.

(c) Price Discovery

This Final Rule may enhance or negatively impact price discovery. Absent the Final Rule, counterparties, in particular smaller counterparties, may have been discouraged from trading uncleared swaps because they may not have been able to secure resources and services in a timely manner to operationalize the exchange of IM. The resultant reduction in uncleared swaps trading may have reduced liquidity and harmed price discovery. Conversely, the delay in implementation of the IM requirements for the Smaller Portfolio Group may cause those counterparties to adjust the pricing of their swaps to incorporate additional risks that would otherwise have been covered by IM. These additional adjustments could result in pricing differentiations between swaps entered into by some Smaller Portfolio Group entities and entities already subject to the margin requirements. As a result, the ability of entities in the Smaller Portfolio Group to compare realized trade prices may be reduced, harming effective market price discovery by these entities.

(d) Sound Risk Management

As discussed above, the Final Rule will delay the compliance date for the Smaller Portfolio Group by one year. As a result, swaps entered into during the one-year period will not be subject to the IM requirements, potentially increasing the level of counterparty credit risk to the financial system. At the same time, the Final Rule will reduce the potential market disruption that could have resulted from the large number of counterparties that would have come into the scope of the IM requirements at the end of the compliance schedule being amended, which would have required compliance by September 1, 2021. The delayed compliance schedule will alleviate the potential disruption in establishing the financial infrastructure for the exchange of IM between in-scope entities and will give counterparties time to prepare for IM compliance and to establish operational processes tailored to their uncleared swaps and associated risks. In addition, to the extent some entities would have been precluded from trading swaps during that one-year period, the rule allows those firms to continue their current risk management practices.

(e) Other Public Interest Considerations

The Final Rule promotes harmonization with international and domestic margin regulatory requirements, reducing the potential for regulatory arbitrage. The Final Rule amends the CFTC Margin Rule consistent with the 2020 BCBS/IOSCO Margin Framework, and the prudential regulators' June 2020 IFR amending the IM compliance schedule.

D. Antitrust Laws

Section 15(b) of the CEA requires the Commission to ''take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the purposes of this Act, in issuing any order or adopting any Commission rule or regulation (including any exemption under section 4(c) or 4c(b)), or in requiring or approving any bylaw, rule, or regulation of a contract market or registered futures association established pursuant to section 17 of this Act.'' [34]

The Commission believes that the public interest to be protected by the antitrust laws is generally to protect competition. The Commission requested comment on whether this Proposal implicates any other specific public

[33] While all entities that are covered by the Commission's margin requirements are required to exchange variation margin, the Commission notes that some entities may not be required to post and collect IM, as certain thresholds must be met before the posting and collection of IM are required.

[34] 7 U.S.C. 19(b).

interest to be protected by the antitrust laws and received no comments.

The Commission has considered this Final Rule to determine whether it is anticompetitive and has identified no anticompetitive effects. The Commission requested comments on whether the Proposal was anticompetitive and, if so, what the anticompetitive effects were, and received no comments.

Because the Commission has determined that this Final Rule is not anticompetitive and has no anticompetitive effects, the Commission has not identified any less anticompetitive means of achieving the purposes of the CEA.

List of Subjects in 17 CFR Part 23

Capital and margin requirements, Major swap participants, Swap dealers, Swaps.

For the reasons stated in the preamble, the Commodity Futures Trading Commission amends 17 CFR part 23 as follows:

PART 23—SWAP DEALERS AND MAJOR SWAP PARTICIPANTS

■ 1. The authority citation for part 23 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 6, 6a, 6b, 6b–1,6c, 6p, 6r, 6s, 6t, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21.

Section 23.160 also issued under 7 U.S.C. 2(i); Sec. 721(b), Pub. L. 111–203, 124 Stat. 1641 (2010).

■ 2. Amend § 23.161 by revising paragraph (a)(7) as follows:

§ 23.161 Compliance dates.

(a) * * *

(7) September 1, 2022 for the requirements in § 23.152 for initial margin for any other covered swap entity for uncleared swaps entered into with any other counterparty.

* * * * *

Issued in Washington, DC, on October 20, 2020, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants—Commission Voting Summary and Commissioner's Statement

Appendix 1—Commission Voting Summary

On this matter, Chairman Tarbert and Commissioners Quintenz, Behnam, Stump, and Berkovitz voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Supporting Statement of Commissioner Brian Quintenz

I support today's final rule that extends the last phase of compliance for initial margin requirements to September 1, 2022. In light of the unprecedented economic and social impacts of COVID–19 and the potential market disruption that could result from a large number of entities coming into scope on September 1, 2021, I strongly support an additional one year deferral for these firms. As I have noted previously, given the large number of firms covered by the final compliance phases, the estimated 7,000 initial margin relationships that need to be negotiated, and the small overall percentage of swap activity these firms represent, a one year delay for these firms is appropriate in order to facilitate an efficient, orderly transition for the market into the uncleared margin regime. In addition, today's final rule also ensures the Commission is consistent with the BCBS–IOSCO recommended margin framework and with actions taken by U.S. prudential regulators to extend the margin compliance schedule.[1]

[FR Doc. 2020–23473 Filed 11–6–20; 8:45 am]

BILLING CODE 6351–01–P

[1] *See* Basel Committee on Banking Supervision and Board of the International Organization of Securities Commissions, Margin Requirements for Non-Centrally Cleared Derivatives (Apr. 2020), *available at https://www.iosco.org/library/pubdocs/pdf/IOSCOPD651.pdf.*

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[SATS No. PA–160–FOR; Docket ID: OSM–2010–0019; SIDIS SS08011000 SX064A000 201S180110; S2D2S SS08011000 SX064A000 20XS5015201]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval, with one exception, of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving, with one exception, an amendment to the Pennsylvania regulatory program (Pennsylvania program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). We are approving regulatory changes that involve the elimination of manganese from the list of pollutants tested for mining discharges when certain weather conditions exist. We are also approving statutory and regulatory changes, with one exception, that involve the treatment of post-mining pollutional discharges on regulated coal mining sites and include provisions involving passive treatment technologies and alternate effluent limitations.

DATES: Effective December 9, 2020.

FOR FURTHER INFORMATION CONTACT: Ben Owens, Field Office Director, Pittsburgh Field Office, Office of Surface Mining Reclamation and Enforcement, Telephone: (412) 937–2827, email: *bowens@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Pennsylvania Program
II. Submission of the Amendment
III. OSMRE's Findings
IV. Summary and Disposition of Comments
IV. OSMRE's Decision
V. Statutory and Executive Order Reviews

I. Background on the Pennsylvania Program

A. Pennsylvania's Regulatory Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the program on July 30, 1982. You can find background information on the Pennsylvania program, including the Secretary's findings, the disposition of comments, and conditions of approval in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions concerning Pennsylvania's program and program amendments at 30 CFR 938.11, 938.12, 938.13, 938.15, and 938.16.

B. Pennsylvania's National Pollutant Discharge Elimination System (NPDES) Program

The Clean Water Act (CWA) (33 U.S.C. 1251 *et seq.*) is based on the principle of federalism, with distinct roles for both the U.S. Environmental Protection Agency (EPA) and the states. The goal of the CWA is to restore and maintain the chemical, physical, and biological integrity of the nation's waters. The CWA generally focuses on two types of controls for point source (single identifiable source of pollution) discharges of pollutants to waters of the United States: (1) Water quality-based controls, based on State water quality standards, and (2) technology-based controls, based on effluent limitations guidelines and standards (ELGS).

Effluent limitation guidelines, which are a subject of this notice, are regulatory standards established by the EPA as part of its NPDES program and apply to different categories of wastewater discharged to surface waters as authorized under section 304(b) of the CWA (33 U.S.C 1314). EPA promulgated regulatory standards for various industrial categories based on the performance of treatment and control technologies. Coal mining industry requirements are found at 30 CFR part 434, *Coal Mining Point Source Category BPT, BAT, BCT Limitations and New Source Performance Standards.*

The EPA standards at part 434 establish limitations on the concentration or quality of pollutants or pollutant properties (*i.e.,* total suspended solids, iron, manganese, and settleable solids), which may be discharged to surface waters as a result of coal mining activity. The parameters and limitations for pollutants differ depending on factors such as the type of site, type of control technology involved, type of drainage, mining status, and weather conditions. These parameters and limitations can be found at subparts B., *Coal Preparation Plants and Coal Preparation Associated Area,* C., *Acid or Ferruginous Mine Drainage,* D., *Alkaline Mine Drainage,* E., *Post-Mining Areas,* and F., *Miscellaneous Provisions.*

Regarding limitations on post-mining areas, we note that in response to a request for clarification from Pennsylvania, EPA concluded in a January 28, 1992, Memorandum that the requirements of 40 CFR part 434 did not expressly apply to groundwater point source seeps discharged to navigable waters from a post-mining reclamation area (Administrative Record No. 853.16). EPA later stated that its position in 1992 does not reflect current EPA regulatory analysis. EPA stated that seepage at a reclamation site (surface mine in stage 2 reclamation as provided for in 30 CFR 800.40(c)(2)) *does* (emphasis added) include water that drains through waste rock, overburden, etc., rather than flows over the surface, and these seepages are subject to the effluent limit guidelines in 434 Subchapter E, *Post-Mining Areas,* which are a subject of this notice. See the *EPA Concurrence and Comments* section later in this notice.

For sources discharging directly to surface waters, permitting authorities must incorporate the EPA-promulgated limitations and standards into discharge permits, where applicable, as required by 40 CFR part 122, *EPA Administered Permit Programs: The National Pollutant Discharge Elimination System.* Effluent limitations serve as the primary mechanism in NPDES permits for controlling discharges of pollutants to receiving waters. When developing effluent limitations for an NPDES permit, a permit writer must consider limits based on both the treatment and control technologies available to control the pollutants (*i.e.,* technology-based effluent limitations and standards (TBELS), which are addressed at 40 CFR part 434, and limits that are based on risks or impacts upon the receiving water (*i.e.,* water quality-based effluent limitations and standards (WQBELS)), which are addressed at 40 CFR part 131, *Water Quality Standards.* WQBELS are included in NPDES permits if TBELS alone are not sufficient to ensure compliance with applicable water quality standards.

A State may assume the role of permitting authority if it has been authorized to administer the NPDES permit program under the authority of sections 3 18, 402, and 405(a) (National Pollutant Discharge Elimination System—NPDES) of the CWA. The Federal regulations at 40 CFR part 123, *State Program Requirements,* provide the procedures EPA follows for approving, amending, and withdrawing a State program that has requested or assumed responsibility for administering the NPDES program under the CWA. Pennsylvania assumed responsibility for the administration of the NPDES program and its program regulations are found at 25 Pennsylvania Code (Pa Code) Chapter 92a, *National Pollutant Discharge Elimination System—Permitting, Monitoring and Compliance.* This regulation prescribes requirements necessary to implement the program under the CWA. Pennsylvania's NPDES regulations at 25 Pa Code § 92a.12, *Treatment Requirements,* at subsection (a)(l) refer to the ELGS established under chapters 87–90 of 25 Pa Code, which pertain to the ELGS for coal mining and are a subject of this notice. Pennsylvania's water resource regulations, which include regulations involving water quality standards and implementation, are found at chapters 91–111 of 25 Pa Code.

II. Submission of the Amendment

A. Statutory and Regulatory Program Changes

By letter dated October 1, 2010, Pennsylvania submitted an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) (Administrative Record No. PA 854.03). We announced receipt of the proposed amendment in the March 25, 2011, **Federal Register** (76 FR 16714), (Administrative Record No. PA 854.08). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because none was requested. The public comment period ended on April 25, 2011. We received comments from a consulting company and an environmental organization, which are addressed in the Public Comments section found later in this **Federal Register** notice.

The amendment submitted to us involves two types of changes: (1) The elimination of manganese from the list of parameters tested for mining discharges when certain weather conditions exist, and (2) the addition of provisions that address the treatment of post-mining pollutional discharges on regulated coal mining sites, including provisions involving passive treatment technologies and alternate effluent limitations. Part of the amendment involves changes initiated by the State (elimination of manganese) and the other part involves changes submitted as a result of a request from us (passive treatment systems and ELGS). These changes are described below. We note that the term ''post-mining pollutional discharges'' is sometimes spelled in the Federal and State regulations with a hyphen and sometimes without a hyphen. In this document the use of ''post-mining pollutional discharges'' with a hyphen will represent both alternative spellings.

1. Regulatory Provisions Involving ELGS Applicable During Precipitation Events

Pennsylvania submitted this change at its own initiative. It involves regulatory changes to the mining regulations at 25 Pa. Code subsections 87.102(a), 88.92(a), 88.187(a), 88.292(a), 89.52(c), and 90.102(a) related to ELGS. These subsections are nearly identical but are found at different parts of the Pennsylvania program as follows: Surface coal mining at 87.102(a); anthracite coal mining activities at sections 88.92(a), 88.187(a), and 88.292(a); underground mining activities at 89.52(c); and coal refuse disposal areas at 90.102(a). These subsections address effluent criteria for discharges occurring or having occurred due to surface and anthracite coal mining activities, underground coal mining, and coal refuse disposal operations.

Pennsylvania's OSMRE-approved regulatory program incorporates all of the ELGS prescribed by EPA for coal mining point sources and incorporates

them at 25 Pa Code chapters 87–91. Pennsylvania's program includes three groups of effluent criteria at these subsections and they are labeled Groups A, B, and C. Group A ELGS apply for pit water, during dry conditions for surface runoff from active surface mining areas, areas where stage 2 standards have been achieved (revegetation has been established), drainage from coal refuse disposal piles, drainage from underground mine workings, and all other discharges; Groups B and C ELGS apply to all of the above discharges except pit water and underground mine workings. Group B ELGS apply when there is an increase in the volume of a discharge caused by precipitation within any 24-hour period less than or equal to a 10-year, 24-hour precipitation event; and Group C ELGS apply to a mining discharge when there is a greater than 10-year, 24-hour precipitation event.

All three groups include discharge limitations that require alkalinity to be greater than acidity and the pH to be greater than 6 but less than 9. The groups differ, however, regarding other parameters. Group A ELGS include iron, manganese, and suspended solids. Group B ELGS include iron, manganese, and settleable solids. Group C does not include any other limitations.

Pennsylvania seeks to revise its regulations by removing manganese from Group B effluent criteria to be consistent with EPA standards at 40 CFR 434.63, *Effluent limitations for precipitation events,* which provide alternate ELGS for discharges during precipitation events. These alternate ELGS are less stringent than those prescribed for discharges during dry conditions and vary depending on factors such as the mining status (active or post-mining), volume of precipitation, type of discharge (alkaline or acid or ferruginous mine drainage), and the type of mine operation or facility that is involved. Because Pennsylvania's regulatory program includes a manganese limitation for discharges during precipitation events at Group B and EPA does not include manganese as a limitation in its regulations at 40 CFR 434.63, Pennsylvania seeks to remove manganese from the list of pollutant limitations required for these discharges.

Pennsylvania states its regulations at 25 Pa Code, Chapter 87, *Surface Mining of Coal,* Chapter 88, *Anthracite Coal,* Chapter 89, *Underground Mining of Coal and Coal Preparation Facilities,* and Chapter 90, *Coal Refuse Disposal,* are consistent with EPA regulations at 40 CFR part 434. Pennsylvania states that its revised regulations are consistent with EPA's regulations under the CWA and that because SMCRA and its implementing regulations require compliance with the CWA, the revised regulations should be approved.

2. Statutory and Regulatory Provisions Involving Treatment of Post-Mining Pollutional Discharges

Pennsylvania submitted additional program provisions in response to a letter from us on July 7, 2010. In the letter, we notified the State that we became aware that the provisions in 25 Pa. Code § 87.102(e), Hydrologic balance: Effluent standards, Post-mining pollutional discharges, while enacted and codified by the State in 1997, had not been submitted to us for approval (Administrative Record No. PA 854.24). In response, Pennsylvania submitted statutory and regulatory changes that address the treatment of post-mining pollutional discharges.

Pennsylvania seeks to revise its program by adding the statutory provisions at section 4.26 (52 P.S. § 1396.4b(j)) of Pennsylvania's Surface Mining Conservation and Reclamation Act (PA SMCRA), 52 P.S. §§ 1396.1–1396.19. Pennsylvania also seeks to revise its program by adding the implementing regulatory provisions at 25 Pa. Code §§ 87.102(e), 88.92(e), 88.187(e), 88.292(e), and 90.102(e) as adopted by Pennsylvania's Environmental Quality Board (EQB) on November 19, 1997. The provisions are nearly identical, but are found at different parts of the Pennsylvania program as follows: Surface coal mining at 25 Pa. Code § 87.102(e); anthracite coal mining activities at 25 Pa. Code §§ 88.92(e), 88.187(e), and 88.292(e); and coal refuse disposal areas at 25 Pa. Code § 90.102(e).

In summary, these new provisions define a post-mining pollutional *discharge* and a *passive treatment system;* establish eligibility criteria for using passive treatment systems to address post-mining pollutional discharges; provide alternate ELGS for qualifying discharges; and prescribe passive treatment design requirements. The changes are described below.

a. *Statutory Changes:* Pennsylvania seeks to add section 4.2(j) of PA SMCRA, which provides for the following:

(1) Authorizes the EQB to revise existing regulations and establish TBELS for classes or categories of post-mining pollutional discharges from surface mining activities that have achieved stage 2 reclamation standards and that the Pennsylvania Department of Environmental Protection determines can be adequately treated using passive treatment systems;

(2) establishes two classes/categories of post-mining pollutional discharges deemed suitable for using passive treatment systems as identified below:

(a) Discharges that have a pH which is always greater than 6.0 and an alkalinity which always exceeds the acidity; or

(b) discharges that have an acidity which is always less than 100 mg/L, an iron content which is always less than 10 mg/L, a manganese content which is always less than 18 mg/L, and a flow rate which is always less than three gallons per minute (gpm);

(3) requires regulations to contain TBELS established using best professional judgment (BPJ);

(4) requires post-mining pollutional discharges to comply with 25 Pa. Code Chapters 92 and 93, relating to NPDES and water quality standards, respectively; and

(5) allows a person to petition the EQB for rulemaking under this subsection.

b. *Regulatory Changes:* Pennsylvania seeks to add regulatory provisions at 25 Pa Code that address the treatment of post-mining pollutional discharges. These new provisions include: Definitions; eligibility criteria for determining discharges that are suitable for the use of passive treatment technologies; alternative ELGS; and passive treatment design requirements. We have summarized these provisions below.

(1) *Definitions:* Pennsylvania seeks to revise section 86.1 by adding two definitions (passive treatment system and post-mining pollutional discharge) to the list of definitions pertaining to the coal mining program.

(a) *Passive Treatment:* Pennsylvania defines passive treatment as a mine drainage treatment system that does not require routine operational control or maintenance. It includes biological or chemical treatment systems, alone or in combinations, as approved by the State, such as artificially constructed wetlands, cascade aerators, anoxic drains, or sedimentation basins.

(b) *Post-mining Pollutional Discharge:* Pennsylvania defines a *post-mining pollutional discharge* as a discharge of mine drainage emanating from or hydrologically connected to the permit area, which may remain after coal mining activities have been completed and which does not comply with the applicable effluent limit requirements of 25 Pa. Code §§ 87.102, 88.92, 88.187, 88.292, 89.52, or 90.12. The term includes ''*minimal-impact post-mining pollutional discharges*'' as defined in

section 3 of PA SMCRA (52 P.S. § 1396.3).

(2) *Treatment of Post-mining Pollutional Discharges:* Pennsylvania seeks to add subsections 87.102(e), 88.92(e), 88.187(e), 88.292(e), and 90.102(e), which address the treatment of post-mining pollutional discharges. We have summarized these provisions below.

(a) *Effluent Limitation Guidelines and Standards:* The provisions at subsections (e)(l) and (e)(2) require the discharger to provide treatment of post-mining pollutional discharges to meet Group A standards, the most stringent standards, and take any measures that are available and necessary to abate the discharge, including modifying the operation and reclamation plan. If, after this interim period, the discharge still exists, the operator must arrange for sound future treatment that will achieve compliance with Group A standards, which involve iron, alkalinity, suspended solids, and manganese. However, if the discharge can be adequately treated using a passive treatment system, alternate standards involving iron and alkalinity apply.

(b) *Eligibility Criteria of Suitable Discharges for Passive Treatment Systems:* The provisions at subsections (e)(2) establish classes or categories of post-mining pollutional discharges deemed suitable for using passive treatment systems. They include, but aren't limited to:

(i) Where pH is always greater than 6.0 and alkalinity always exceeds acidity;

(ii) where acidity is always less than 100 mg/L, iron is always less than 10 mg/L, manganese is always less than 18 mg/l, and flow is always less than 3 gpm; and

(iii) where net acidity is always less than 300 mg/L. Net acidity is calculated by subtracting the alkalinity of the discharge from its acidity.

(c) *Alternate ELGS:* The provisions at subsections (e)(3) prescribe alternate ELGS if the untreated discharge can be adequately treated using a passive treatment system. The following effluent limitations apply in lieu of those in Group A:

(i) Reduce the iron concentration by at least 90 percent or by the percentage necessary to achieve Group A effluent requirements, whichever percentage is less; and

(ii) produce an effluent alkalinity which exceeds effluent acidity.

(d) *Passive Treatment System Design:* The provisions at subsections (e)(4) and (e)(5) require that passive treatment systems be designed to prevent leakage of mine drainage into the groundwater system; prevent groundwater and surface water runoff Lin-impacted by mining from entering the treatment system; hydraulically handle the highest average monthly flow-rate which occurs during a 12-month period; have inlet and outlet structures which allow for flow measurements and water sampling; prevent to the maximum extent possible physical damage and associated loss of effectiveness due to wildlife and vandalism; and be of a capacity so that they will operate effectively and achieve the required effluent quality for 15 to 25 years before needing to be replaced. The provisions require the system to be designed by and constructed under the supervision of a qualified professional knowledgeable in the subject of passive treatment of mine drainage.

Pennsylvania contends that these changes are consistent with EPA's 1992 guidance memorandum (see discussion below). Specifically, Pennsylvania references the 1992 EPA memorandum relating to the applicability of 40 CFR part 434 to post-mining discharges from surface mines and points out that the memorandum confirmed that certain post-mining discharges are not addressed in 40 CFR 434. Pennsylvania states its provisions are consistent with the memorandum because the memorandum provides that in the absence of established ELGS, technology-based limits are developed on a best professional judgment (BPJ) basis.

B. Supporting References and Documents

In addition to the statutory provisions and revised regulations submitted for approval, Pennsylvania also provided an Analysis Document to assist with our review. It includes citations of OSMRE regulations at 30 CFR 816.42 and 817.42 (*Hydrologic balance: Water quality standards and effluent limitations,* for surface mining and underground mining respectively) and EPA regulations at 40 CFR part 434, *Coal Mining Point Source Category BPT, BAT, BCT Limitations and New Source Performance Standards.* It also references the following documents:

1. *EPA Memorandum dated January 28, 1992, addressed to Pennsylvania Department of Environmental Resources, and entitled ''Application of 40 CFR Part 434 to Post-Mining Ground Water Point Source Seeps from Surface Mines''*

The EPA, in response to a request for clarification from Pennsylvania, concluded in this memorandum that the requirements of 40 CFR part 434 do not expressly apply to groundwater point source seeps discharged to navigable waters from a post-mining reclamation area. The EPA suggested that Pennsylvania establish TBELS for post-mining groundwater seeps from reclamation areas using BPJ, provided sufficient facts support control of the discharge by an NPDES permit and provided it is appropriate to impose TBELS, rather than WQBELS.

2. *Pennsylvania Report dated 1994, entitled ''Best Professional Judgment Analysis for the Treatment of Post-mining Discharges from Surface Mining Activities''*

This report is used to support Pennsylvania's reliance on BPJ, in the absence of EPA-prescribed TBELS, to establish the treatment requirements for post-mining pollutional discharges.

C. Supplemental Information

As required by Federal regulations at 30 CFR 732.17(h)(11)(ii), we are required to obtain written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the CWA (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (CAA) (42 U.S.C. 7401 *et seq.*). The revision that Pennsylvania proposes to make in this amendment pertains to water quality standards. Therefore, we asked EPA to comment and provide concurrence regarding the amendment.

During the amendment review process, we communicated with EPA and Pennsylvania on several occasions. The information obtained through the interaction between us, EPA, and Pennsylvania is germane to our findings. We summarize the communications in the *EPA Concurrence and Comments* section found later in this **Federal Register** document. Our findings should be read along with that section in order to fully understand the rationale that led to our decision.

III. OSMRE's Findings

The following are the findings we made concerning the amendment under SMCRA at 30 U.S.C. 1253 and the Federal regulations at 30 CFR 732.15, *Criteria for approval or disapproval of state programs,* and 30 CFR 732.17, *State program amendments.* We are approving, with one exception, the amendment as described below.

A. Effluent Limitations Applied During Precipitation Events

Federal SMCRA at subsections 515(b)(10) and 516(b)(9) (30 U.S.C.1265(b)10) and 30 U.S.C. 1266(b)(9)) and the Federal regulations at 30 CFR 816.41 and 817.41,

Hydrologic-balance protection, for surface mining and underground mining respectively, require that surface coal mining and reclamation operations be conducted to minimize disturbance to the prevailing hydrologic balance and to the quantity and quality of water in surface water and groundwater systems, both during and after mining and during reclamation. In addition, subsections 510(b)(2) and (3) of SMCRA (30 U.S.C. 1260(b)(2) and (3)) and 30 CFR 773.15, *Written findings for permit application approval,* subsections (b) and (e) prohibit the regulatory authority from approving a permit application unless the applicant has demonstrated that reclamation can be accomplished and that the proposed operation has been designed to prevent material damage to the hydrologic balance outside the permit area.

The regulations at 30 CFR 816.41 and 817.41 require that, among other things, mining and reclamation practices that minimize water pollution and changes in flow must be used in preference to water treatment. Consistent with this approach, subsection (b)(l) and (d)(l) of 816.41 and 817.41 require that surface water and ground water quality must be protected by handling earth materials and runoff in a manner that minimizes the formation of acid and toxic forming materials. However, when water treatment is unavoidable, sections 816.42 and 817.42 specify that discharges must be made in compliance with applicable State and Federal water quality laws, regulations, and effluent limitations. These effluent limits and water quality standards include all applicable State and Federal water quality laws and regulations, including the ELGS for coal mining as promulgated by EPA and set forth in 40 CFR part 434.

The EPA regulations at section 40 CFR 434.63 provide alternate limitations for discharges during precipitation events and they apply to discharges involving surface mining, coal prep plants, coal refuse disposal areas, and reclamation areas. This section does not apply to discharges from underground workings of an underground mine, unless comingled with other eligible discharges. We note that section 434.63 does not provide a manganese limitation for any precipitation event.

There are no specific OSMRE regulations addressing effluent limitations; however, we note that OSMRE regulations included ELGS for surface coal mining and reclamation operations at one time. On October 22, 1982, these standards were removed and replaced with a reference in 30 CFR 816.42 and 30 CFR 817.42 to EPA's effluent limitation standards. *See* 47 FR 47216, October 22, 1982, and 48 FR 44006, September 26, 1983. This was done to eliminate unnecessary duplication and confusion between EPA's and OSMRE's standards and establish EPA as the responsible Federal agency for developing ELGS as they relate to coal mining activities. We note that Pennsylvania did not submit the proposed ELGS changes to EPA for approval. Because Pennsylvania's regulatory program incorporates, rather than references, ELGS in its coal mining regulations at 25 Pa Code Chapters 87–91, we received this amendment for processing. We sought EPA's concurrence on the changes during the review process. (*See* the EPA Concurrence and Comments section later in this notice.)

OSMRE Finding: EPA's regulations at 40 CFR 434.63 do not require a manganese limitation for any precipitation event. Pennsylvania's elimination of manganese from Group B ELGS is consistent with EPA's requirements. For this reason and given EPA's concurrence, we find that the proposed revisions at 25 Pa. Code §§ 87.102(a), 88.92(a), 88.187(a), 88.292(a) 89.52(c), and 90.102(a) are consistent with the Federal regulations at 30 CFR 816.42 and 30 CFR 817.42, which require compliance with EPA effluent standards. Therefore, we are approving them.

B. Treatment of Post-Mining Pollutional Discharges

There are no provisions or comparable definitions included in Federal SMCRA or OSMRE's regulations that address the treatment of post-mining pollutional discharges or the use of passive treatment systems. However, mechanisms to address unexpected post-mining pollutional discharges are necessary because it is beyond dispute that, despite best management practices, post-mining pollutional discharges may occur. Varying methods of treatment are employed to treat these unexpected discharges, including passive treatment systems. Passive treatment systems require ongoing operation and maintenance activity, but less frequent monitoring and continuous management than active treatment systems. Our policy directive, OSMRE Directive TSR–IO, *Use of Wetland Treatment Systems for Coal Mine Drainage,* explains our position regarding the use and benefits of wetland treatment systems, a form of passive treatment, for coal mine drainage. In TSR–10, we explain that because neither SMCRA nor its implementing regulations place limitations on the methodology used to treat acid or ferruginous discharge, we will neither promote nor discourage the use of constructed wetlands for treatment of mine drainage. This includes mine drainage that may or may not be net acidic.

Pennsylvania's statutory provisions of section 4.2(j) of PA SMCRA, authorize Pennsylvania to: Revise existing regulations and establish TBELS for classes or categories of post-mining pollutional discharges that have achieved stage 2 reclamation standards and that Pennsylvania determines can be adequately treated using passive treatment systems; prescribe two categories of discharges deemed suitable for such treatment; require regulations to contain TBELS established using BPJ; require post-mining pollutional discharges to comply with NPDES and water quality standards; and allow a person to petition the EQB for rulemaking.

We are approving the statutory language along with the implementing regulations, with one exception, for the reasons described below.

1. Definitions

There are no comparable definitions of post-mining pollutional discharge or passive treatment system in Federal SMCRA or its implementing regulations. The definition of minimal-impact post-mining discharge, which is incorporated into Pennsylvania's definition of post-mining pollutional discharge at PASMCRA (52 P.S. § 1396.3), has not been approved as part of the Pennsylvania program.

We previously reviewed statutory and regulatory changes effected by Act 173, which included changes to 52 P.S. 1396.3, Definitions. We addressed the definition of minimal-impact post-mining discharge in a May 13, 2005, **Federal Register** notice (70 FR 25474) (Administrative Record No. 853.53). In that notice, which documented our findings pertaining to Pennsylvania Program Amendment No. PA–124, we summarized the statutory provisions of sections 4(g.1), (g.2), and (g.3) of PA SMCRA (52 P.S. §§ 1396.4(g.1), (g.2), and (g.3)). These sections pertain to bond release at sites with post-mining pollutional discharges, and bond release at sites with minimal-impact post-mining discharges.

In a letter dated December 23, 2003, Pennsylvania requested that we remove the statutory provisions of 1396.4(g.1), (g.2), and (g.3) from the PA–124 program amendment submission because its statutory definition of *minimal-impact post-mining discharge* at 52 P.S. § 1396.3 and the regulations for post-mining pollutional discharges

were not included in the proposed program amendment (Administrative Record No. 853.23). We granted that request and did not take any action with respect to proposed sections 4(g.1), (g.2), and (g.3).

OSMRE Finding: Based on Pennsylvania's earlier request that we not take any action with respect to proposed statutory provisions of 52 P.S. §§ 1396.4(g.1), (g.2), and (g.3), we never approved the definition of *minimal-impact post-mining discharge.* For the reasons mentioned above and because it is not inconsistent with SMCRA and the implementing Federal regulations, we are approving the regulatory definition of *post-mining pollutional discharge* at 25 Pa. Code § 86.1, except for the reference to *minimal impact post-mining discharges.* We are deferring our decision on the inclusion of minimal impact post-mining discharges in the definition of post-mining pollutional discharge until such time as the State submits the definition of minimal-impact post-mining discharge to us as a proposed program amendment. We are also approving the regulatory definition of *passive treatment system* at 25 Pa. Code § 86.1 because it is not inconsistent with SMCRA and the implementing Federal regulations.

2. Statutory Provisions and Eligibility Criteria for Suitable Discharges for Passive Treatment Systems

As stated above, there are no direct Federal counterparts to these amendments, either in SMCRA or in its implementing regulations. However, neither SMCRA nor its regulations prohibit the use of passive treatment on bonded sites with post-mining pollutional discharges. Moreover, SMCRA and its regulations are devoid of any threshold criteria authorizing the use of passive treatment systems on these sites.

We note that while the statutory provisions at 4.2(j) of PA SMCRA identify two categories of discharges suitable for passive treatment, the regulatory provisions identify three categories as noted under the description of the regulatory changes at 25 Pa. Code §§ 87.102(e), 88.92(e), 88.187(e), 88.292(e), and 90.102(e) above. The third category, which is included in the regulations, requires net acidity to always be less than 300 mg/L. In its program amendment submission letter, Pennsylvania states that its 1994 BPJ analysis supports the addition of the third category. In addition, the regulations allow Pennsylvania to extend the passive treatment authority to other discharges it deems appropriate.

We asked Pennsylvania about the discrepancy between the statutory and regulatory provisions. In an email correspondence to us from Pennsylvania dated November 10, 2014, Pennsylvania stated that all of the regulations included in this amendment were adopted under the rulemaking authority of section 4.2(a) of the PA SMCRA (52 P. S. § 1396.4b(a)); section 5(b) of The Clean Streams Law (CSL) (35 P. S. § 691.5(b)); section 3.2(a) of the Coal Refuse Disposal Control Act (CRDCA) (52 P. S. § 30.53b(a)); and section 1920–A of the Administrative Code of 1929 (71 P. S. §§ 510–20) which authorizes the EQB to adopt regulations necessary for the Department to perform its work. (Administrative Record No. PA 854.23).

OSMRE Finding: There is no prohibition of the use of passive treatment technologies on bonded sites with pollutional discharges, in either SMCRA or its implementing regulations. Pennsylvania's provisions prescribing criteria for post-mining discharges deemed suitable for passive treatment are consistent with the conclusions of its 1994 BPJ analysis. With regard to the eligibility criteria and the discrepancy between the two statutory provisions and the three regulatory provisions, we find that Pennsylvania has demonstrated it has the general statutory authority to augment its regulations, and that it properly exercised that authority. We find the statutory and regulatory provisions, will result in construction of treatment systems for post-mining pollutional discharges, which minimize disturbance of the hydrologic balance within the permit and adjacent areas, and prevent material damage to the hydrologic balance outside the permit area as required by 30 CFR 816.41(a). For the reasons mentioned above, we find the statutory provisions at section 4.2(j) of PA SMCRA and the regulatory provisions at subsection (e)(l) and (e)(2) of sections 87.102, 88.92, 88.187, 88.292, and 90.102 are not inconsistent with SMCRA and its implementing regulations, and, therefore, we are approving them.

3. Alternate ELGS

Pennsylvania's provisions at subsections (e)(3) of sections 87.102, 88.92, 88.187, 88.292, and 90.102 provide for alternate ELGS that apply to post-mining pollutional discharges when passive treatment systems are authorized and Group A standards cannot be achieved. These alternate provisions do not involve limitations for manganese and suspended solids as required under Group A standards. When authorized, these ELGS apply to these post-mining pollutional discharges in addition to the ELGS prescribed by the EPA. EPA regulations at 40 CFR 434.52, *Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control,* provide an effluent requirement for discharges emanating from post-mining areas (reclamation areas until the performance bond issued to the facility by the appropriate SMCRA authority has been released). The regulation at subsection (a) of this section requires that the discharge have no more than 0.5 ml/L of settleable solids and a pH of between 6 and 9. We noted that Pennsylvania does not have ELGS involving settleable solids or pH for post-mining pollutional discharges from surface reclamation areas in its program submission.

When we asked EPA about this omission, EPA responded that all discharge limits must be consistent with the CWA regardless of SMCRA or other applicable regulations. This means that, in accordance with section 301 of the CWA (33 U.S.C. 1311) and 40 CFR 122.44, *Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs),* the more stringent of TBELS or WQBELS must be used to control point source discharges. Regardless of whether a TBEL or WQBEL is applied, any discharge must still meet all water quality standards.

EPA advised that any NPDES permit issued by PADEP for post-mining pollutional discharges must still address pH and settleable solids limits. EPA advised that NPDES permits require pH discharges at levels between 6.0 and 9.0 unless a variance is granted pursuant to 40 CFR 434.62. This variance allows the pH level to exceed 9.0 to a small extent, where the application of neutralization and sedimentation technology that slightly elevates the pH also results in the ability to comply with the manganese limitations. Similarly, settleable solids must meet applicable TBELS or WQBELS, even if there is no specific limit identified in 25 Pa. Code Chapters 87, 88, 89, and 90. The NPDES settleable solids permit limit is a maximum being implemented of 0.5 ml/L. Therefore, we understand that NPDES permits issued for post-mining pollutional discharges subject to subsections 87.102(e), 88.92(e), 88.187(e), 88.292(e), and 90.102(e) from surface reclamation areas must meet the ELGS of 40 CFR 434.52(a) in addition to requirements of the chapters cited above. Pennsylvania's program requires strict adherence to the applicable ELGS contained in 25 Pa. Code §§ 87.102(a),

88.92(a), 88.187(a), 88.292(a), and 90.102(a) until the construction of a passive treatment system is approved, at which time the requirements of subsections (e), which involve alternate limitations, apply.

OSMRE Finding: Pennsylvania's regulations authorizing alternate limitations using passive treatment systems to address post-mining discharges at subsections (e)(3) are consistent with the conclusions of its 1994 BPJ analysis. The EPA has concluded and Pennsylvania has confirmed, that EPA's ELGS involving pH and settleable solids are still required under NPDES permits. In addition to the NPDES program requirements, Pennsylvania is required to meet all Federal and State water quality requirements. Therefore, given that EPA has provided concurrence for the amendment and for the reasons mentioned above, we find that the provisions at subsections (e)(3) of sections 87.102, 88.92, 88.197, 88.292, and 90.102 are not inconsistent with SMCRA and the implementing Federal regulations, and we are approving them.

4. Passive Treatment Design

As mentioned previously, there are no direct Federal counterparts to these amendments, either in SMCRA or in its implementing regulations that address passive treatment system, including design requirements for the construction and performance of such systems. Pennsylvania advises that regulatory design and performance standards at subsections (e)(4) and (e)(5) of 25 Pa. Code §§ 87.102, 88.92, 88.187, 88.292, and 90.102 will help ensure appropriate treatment systems are authorized. Pennsylvania has provided assurances that decisions regarding treatment of post-mining pollutional discharges will be made using current knowledge of passive treatment technology tools for evaluating the use of passive treatment and limitations of passive treatment technologies. Also, permit revision applications to construct passive treatment systems for post-mining pollutional discharges will be subject to the review of qualified agency staff with experience in passive treatment. For the reasons mentioned above, we find the provisions at subsections (e)(4) and (e)(5) of 25 Pa. Code §§ 87.102, 88.92, 88.187, 88.292, and 90.102 are not inconsistent with SMCRA and the implementing Federal regulations, and we are approving them.

IV. Summary and Disposition of Comments

Public Comments

In the March 25, 2011, **Federal Register** notice announcing our receipt of this amendment, we asked for public comments (76 FR 16714). The comment period closed on April 25, 2011. No requests for public meetings or hearings were received. We received comments from a consulting firm (Hedin Environmental) on April 24, 2011 (Administrative Record No. PA 854.11). We also received public comments from one environmental organization, Citizens for Pennsylvania's Future (PennFuture), on two occasions (April 25, 2011, Administrative Record No. PA 854.09, and January 18, 2012, Administrative Record No. PA 854.14). We discuss these comments below.

Hedin Environmental: Hedin Environmental (Hedin), which specializes in the passive treatment of contaminated coal mine drainage, commented that experience and data demonstrates that when passive systems are properly designed, acidity, iron, and aluminum contaminants are reliably decreased to concentrations compliant with the proposed effluent standards. Hedin stated that passive treatment techniques are available for manganese removal; however, this treatment is less reliable.

Hedin further commented that all treatment technologies, including passive treatment technologies, fail when improperly designed. Even though the proposed amendment requires that treatment systems be designed by qualified personnel, Hedin proposes that OSMRE consider strengthening this requirement. Hedin stated that ineffective passive treatment systems have been designed by professional engineers without adequate experience and knowledge of passive technologies and design principles. Hedin opined that the problem is due, in part, to inexperienced engineer's improper use of the OSMRE's AMDTreat software program, a computer program developed to estimate treatment costs for mining discharges. Hedin noted that neither OSMRE nor Pennsylvania has a program that trains professionals in the design of passive treatment systems or provides accreditation for qualified professionals and that this should be corrected.

OSMRE's Response: We agree with the comment that there are no Federal regulations pertaining to the design of passive treatment systems. Likewise, the Federal regulations do not prohibit the use of passive treatment systems on bonded sites with post-mining pollutional discharges. OSMRE concludes that the regulation requiring that the treatment system be designed by and constructed under the supervision of a qualified, professional knowledgeable in the subject of passive treatment of mine drainage is within the discretion of the PADEP. Additionally, if the passive treatment system fails to maintain a discharge within applicable water quality standards or effluent limits, the permittee will be subject to enforcement actions by PADEP and be required to modify the treatment system to ensure that it satisfies the established effluent limits in the applicable NPDES permit.

Pennsylvania has provided assurances that decisions regarding treatment of post-mining pollutional discharges will be made using current knowledge of passive treatment technology tools for evaluating the use of passive treatment and limitations of passive treatment technologies. Also, permit revision applications to construct passive treatment systems for post-mining pollutional discharges will be subject to the review of qualified agency staff with experience in passive treatment. Pennsylvania advises that regulatory design and performance standards will help ensure appropriate treatment systems are authorized. Those standards are discussed in Technical Guidance Directive 563–2112–608, *Constructed Wetlands for Mine Drainage Treatment,* and Technical Guidance Directive 563–0300–101, *Engineering Manual for Mining Operations;* Chapter 6, *Mine Drainage Treatment Facilities.*

We agree with the commenter that an improperly designed passive treatment system substantially increases the likelihood of partial or total system failure. Flawed designs can occur for any number of reasons including insufficient or inaccurate baseline data (flow rates and/or geochemistry), changed flow conditions, construction modifications, constrained site conditions, and poor engineering decisions. However, Pennsylvania regulations have safeguards in place to protect against passive treatment system failures. For example, the Pennsylvania regulation at 25 Pa. Code § 87.117, *Hydrologic Balance: Surface water monitoring,* requires a permit holder to monitor and accurately measure and record the water quantity and quality of surface water to accurately assess discharges from the permit area and the effect of the discharge on the receiving waters. The monitoring of the flow and chemistry of post-mining pollutional discharges must be sufficient to enable the making of informed decisions regarding the type and scale of

treatment to be implemented. The Pennsylvania program requires that surface water be monitored for parameters that relate to the suitability of the surface water for current and approved post-mining land uses and to the objectives for protection of the hydrologic balance. Furthermore, module 8 of the permit application dictates how the baseline surface waters information is to be collected and the frequency.

Moreover, we note that OSMRE's AMDTreat software has been recognized as an industry standard for estimating all types of long-term mine drainage treatment costs. It provides for comparison of treatment costs for multiple systems and facilitates the development of long-term financial forecasting so that practical funding decisions can be made. AMDTreat is just one tool to be used for engineering design by experienced practitioners. Like any engineering tool, AMDTreat can be misapplied or used improperly. To avoid misapplication or improper use, OSMRE provides on-line tutorials for AMDTreat users, makes itself available for user questions, and provides outreach to users through various technical forums. OSMRE also provides training on the use of AMDTreat and on the theory and application of passive treatment technologies to regulatory authority personnel through its National Technical Training and Technical Innovations and Professional Services programs (TIPS).

We disagree with Hedin's assertion that OSMRE does not train professionals in the design of passive treatment systems. Through its TIPS training program, OSMRE offers a course for State and Tribal employees entitled ''Passive Treatment: Theory and Application Workshop.'' This course provides information and exercises that are highly interactive and can be used to evaluate the characteristics of coal mine drainage and guide the selection and application of various passive treatment technologies designed to mitigate the impacts of discharges. For individuals or firms in the private sector, numerous educational programs on passive water treatment design are available from higher-education institutions or private entities. While we acknowledge the commenter's suggestion related to establishing an accreditation for the training of professionals in the design of passive treatment systems, neither SMCRA nor the Federal regulations currently provide for such a requirement. We conclude that the State program has the discretion to determine the design of any passive treatment system, which includes the selection of a qualified professional engineer to design and implement passive treatment systems.

PennFuture: PennFuture's comments were limited to the provisions relating to the establishment of TBELs for post-mining pollutional discharges using BPJ. PennFuture provided the following two comments for our consideration:

a. *EPA Approval:* PennFuture stated that to avoid creating a conflict, OSMRE should not approve the provisions at issue as an amendment to the State regulatory program unless EPA first (or simultaneously) approves them as a revision to Pennsylvania's NPDES program. PennFuture cited EPA regulations governing state NPDES permitting program approvals and contends that EPA must first approve this change because it involves NPDES requirements; therefore, OSMRE, approval should only take place after this has occurred. PennFuture states that when it comes to approving regulations that implement BPJ, EPA should provide approval first because BPJ determinations are required by and governed by the CWA and EPA's NPDES program regulations. As such, PennFuture states Pennsylvania should not implement its post-mining pollutional discharge regulations until they have been approved by EPA as a revision to its approved NPDES program under the CWA. PennFuture contends that unless and until EPA grants approval of Pennsylvania's proposed, categorical BPJ determinations through a formal approval of them as part of the Pennsylvania's NPDES program, OSMRE should not confuse the issue by approving them as part of Pennsylvania's approved regulatory program under SMCRA.

OSMRE's Response: In its May 20, 2014, response to us, EPA noted that there had been numerous amendments to Pennsylvania's water quality chapters in Pa. Code Title 25, *Environmental Protection,* many of which would require EPA approval to become effective under the CWA. EPA, nevertheless, gave OSMRE its concurrence on August 20, 2013, in accordance with 30 CFR 732.17(h)(11)(ii). The question of whether the State's effluent limitations are effective under the CWA must be addressed to, and answered by, the EPA.

Regarding approval of the 1994 BPJ analysis, EPA's clarification of its 1992 Memorandum essentially moots this point. EPA stated that all post-mining discharges from a permitted surface mine reclamation area must have an NPDES permit and meet the effluent limits of 40 CFR 434.52(a), which require limitations involving pH and settleable solids for permitted reclamation areas. Pennsylvania has provided assurances that its implementing regulations will protect the hydrologic balance as required by 30 CFR 816.41 (a) and satisfy all the requirements of State and Federal water quality laws and regulations and comply with ELGS promulgated by EPA under 40 CFR part 434.

b. *Categorical Treatment Requirements and BPJ:* PennFuture states ''[b]linding, categorical treatment requirements of indefinite duration based on an analysis performed nearly two decades ago conflict with the [F]ederal and [S]tate water quality regulations governing BPJ.'' PennFuture contends that, because EPA does not apply ELGS to post-mining pollutional discharges from surface mines, Federal and State water quality laws and regulations governing BPJ can be complied with by Pennsylvania coal operators if limits are established on a permit-by-permit basis, rather than by standardized, categorical treatment requirements. The regulations proposed by Pennsylvania fail to meet this requirement, according to PennFuture, because they ''conflict with the four fundamental attributes of BPJ determinations under EPA's NPDES regulations.'' These attributes, PennFuture states are: (1) BPJ is case-by-case, not categorical; (2) BPJ is flexible, not fixed and binding; (3) BPJ determinations are updated regularly, and not of indefinite duration; and (4), ''BPJ is up to the minute, not stuck in the 1990s.''

OSMRE's Response: We disagree with the comment. An underlying assumption upon which all of PennFuture's arguments are based is that EPA has no ELGS that apply to post-mining pollutional discharges from surface mines. That was the case when EPA's 1992 Memorandum was released, but it is not the case now. EPA has since stated that mine drainage includes ''any drainage and any water pumped or siphoned, from an active mining or a post-mining area.'' (emphasis added) (Administrative Record No. 854.17, citing 40 CFR 434.11 (definition of ''*mine drainage.*'')). The specific ELGS applicable to post-mining areas may be found at the CWA regulation, 40 CFR 434.52. This provision establishes the ELGS for discharges from reclamation areas until the performance bond has been released. Because the effluent limits of 40 CFR 434.52 apply to post-mining pollutional discharges, use of the 1994 BPJ is no longer applicable except as a basis for the Pennsylvania Legislature's direction to allow passive

treatment for a certain type of post-mining discharge. PADEP has committed to following the ELGS of 40 CFR 434.52 for post-mining discharges through the proposed amendments to its regulations and NPDES permits for the treated discharges.

The CWA regulations, at 40 CFR 125, *Criteria and Standards for the National Pollutant Discharge Elimination System,* establish the standards and criteria for the imposition of technology-based treatment systems. These requirements represent the minimum level of control that must be imposed on NPDES permits. It is only in the absence of such ELGS that BPJ-based, permit-specific limits may be imposed. 40 CFR 125.3(c)(2). Because ELGS are in place for post-mining pollutional discharges from surface mines, BPJ determinations are not required. However, Pennsylvania may promulgate permit-specific, BPJ-based discharge limitations, so long as they supplement, rather than supplant, the ELGS promulgated by the EPA. The statutory portion of this program amendment authorizes the PADEP to do precisely that. 52. P.S. § 1396.4b(j). Post-mining pollutional discharges that qualify for passive treatment must comply with the applicable Federal ELGS for post-mining discharges at 40 CFR 434.52(a), and with the additional requirements imposed by 25 Pa. Code § 87.102(e)(3), and with applicable water quality standards, where those standards are more stringent than the Federal ELGS.

Finally, as noted above in response to another comment, Pennsylvania has provided assurances that decisions regarding treatment of post-mining pollutional discharges will be made using current knowledge of passive treatment technology tools for evaluating the use of passive treatment, and limitations of passive treatment technologies. Also, permit applications to construct passive treatment systems for post-mining pollutional discharges will be subject to the review of qualified agency staff with experience in passive treatment. Pennsylvania advises that regulatory design and performance standards will help ensure appropriate treatment systems are authorized and covered by bond or other financial assurance.

Federal Agency Comments

On October 15, 2010, under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Pennsylvania program (Administrative Record No. PA 854.04). The summary of the responses are described below.

The Mine Safety and Health Administration (MSHA), District 1, in a letter dated November 9, 2010, responded that it does not have any comments or concerns with this request (Administrative Record No. PA 854.05).

The U.S. Fish and Wildlife Service (USFWS), in a letter dated April 27, 2011, provided comments regarding the proposed amendment (Administrative Record No. PA 854.10). Its comments were limited to the establishment of limitations addressing manganese in post-mining pollutional discharges. The USFWS noted that technology based treatment requirements using BPJ are prescribed when EPA ELGS do not exist. The USFWS provided comments involving manganese and the effects on fish and wildlife resources.

The USFWS stated that tolerance limits for fish and macroinvertebrate populations reported in the literature vary widely for manganese and are dependent on the individual test organism. According to the USFWS, less information was available, at least as of 2011, on the effects of elevated manganese concentrations on aquatic life than the effects of other metals associated with acid mine drainage, such as iron and aluminum. Research has found correlations between dissolved metals that are at or near toxic levels for fish and invertebrates and the associated levels of these metals in tissues of fish and invertebrates. These levels are shown to have impacts on populations of trout and invertebrates. The USFWS stated that, based on the limited literature available at that time, manganese toxicity appears to have the potential to negatively impact the aquatic life in receiving streams of discharges that would fall under this amendment.

USFWS questioned whether factors such as maintaining the biological integrity of the receiving stream have been considered on these sites where Pennsylvania is using BPJ, which, according to the USFWS, must be used when setting a limit for manganese because manganese is a non-priority pollutant under section 304(a) of the C WA, (33 U.S.C. 1314), and has no ELGS in fresh water.

OSMRE's Response: We forwarded the question about the biological integrity of the stream from manganese discharges to EPA by letter dated January 20, 2014 (see summary of the letter under the EPA Concurrence and Comments section below). EPA responded by letter dated May 20, 2014 (discussed in the section that follows). The EPA response stated that under 40 CFR 122.44(d)(1)(ii), Whole Effluent Toxicity (WET) testing can and should be used to ensure discharges are not toxic and dangerous to aquatic life. EPA also noted 25 Pa. Code § 93.6, General Water Quality Criteria, which states in part, ''[w]ater may not contain substances attributable to point or nonpoint source discharges in concentration or amounts sufficient to be inimical or harmful to the water uses to be protected or to human, animal, plant or aquatic life.'' As such, this regulation requires protection of the biological integrity of receiving streams. EPA further advised that it is in discussions with Pennsylvania about the need to include WET testing requirements in mining NPDES permits. However, Pennsylvania does not use WET testing on mine permits. Instead, at the approval of the EPA, Pennsylvania uses Osmotic Pressure to assess impacts of mine discharges on receiving streams.

Further, by letter of July 2, 2014 (discussed in the section that follows), EPA clarified that all Pennsylvania streams are designated potable water supply (PWS) and that, pursuant to 25 Pa. Code § 96.3(c), manganese is a PWS standard and subject to compliance with in-stream water quality criteria of a maximum of 1 mg/L, to be measured at the point of discharge. Although there is no manganese effluent limit for post-mining discharges from surface mines under 40 CFR 434.52, Pennsylvania regulations at 25 Pa. Code § 96.3, *Water quality protection requirements,* and, by reference, 25 Pa. Code § 93.7(a), *Specific water quality criteria,* are governing. PADEP has committed to requiring a post-mining pollutional discharge to be treated sufficiently by the discharger to meet the more stringent of the applicable technology-based effluent limits or the water quality standards in Chapters 91–96, including the iron and manganese criteria for aquatic life and potable water supply use protection in Chapter 93 through its coal mining regulatory program. Because EPA has classified all streams in Pennsylvania as PWS, thus subject to the 1 mg/L manganese standard, we conclude that compliance with these standards will meet the requirements of SMCRA and the CWA, regarding protection of the biological integrity of streams from manganese effluent from surface mining post-mining discharges. Based on the fact that Pennsylvania conducts testing in streams for monitoring biodiversity, we find Pennsylvania's implementing policies to protect the biological integrity of the streams.

Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to obtain written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the CWA (33 U.S.C. 1251 *et seq.*) or the CAA (42 U.S.C. 7401 *et seq.*). The revision that Pennsylvania proposes to make in this amendment pertains to water quality standards. Therefore, we asked EPA to concur on the amendment in a letter dated October 13, 2010 (Administrative Record No. 854.04). The EPA provided its conditional concurrence on August 20, 2013, and clarification on May 20, 2014, and March 26, 2015 (administrative record numbers are identified below). Prior to providing its concurrence, EPA had communicated with us on several occasions and we and/or Pennsylvania responded to their concerns and comments. The entire content of the letters and communications can be found in the administrative record. We summarize the communications below:

1. *OSMRE's First Letter to EPA:* We submitted the proposed program amendment to EPA for review, comment, and concurrence on October 13, 2010 (Administrative Record No. PA 854.04).

EPA sent us its first response to the proposed amendment on February 10, 2011, (Administrative Record No. PA 854.07), and concluded that it could not provide concurrence because of insufficient information contained in the submission. In order to provide concurrence, EPA requested additional information regarding: The definitions of passive treatment and post-mining pollutional discharge; classes/categories of discharges suitable for passive treatment; NPDES modifications; Pennsylvania's use of BPJ as documented in 1994; and manganese/water-quality based ELGS. The letter reaffirmed that compliance with the CWA is an integral part of SMCRA, and that Pennsylvania's permitting program must comply with regulations implementing the NPDES program and compliance with the CWA before approval or denial of new, modified, amended, or renewed permits.

Pennsylvania responded to EPA's February 10, 2011, letter by sending us a letter on December 9, 2011 (Administrative Record No. PA 854.12). Pennsylvania stated that subsection 87.102(e) establishes treatment standards for post-mining pollutional discharges from surface coal mining operations that are designed to supplement the ELGS established by EPA. Pennsylvania pointed out that the only EPA-established ELGS for post-mining areas on surface mines are that discharges may not exceed 0.5 ml/L maximum for settleable solids and pH must be maintained in the range of 6.0 to 9.0 at all times.

Pennsylvania also stated that dischargers are required to provide interim treatment to comply with Pennsylvania's Group A effluent requirements. These requirements include limits for iron, manganese, suspended solids, and alkalinity. In addition, Pennsylvania stated that a post-mining pollutional discharge must be treated sufficiently by the discharger to meet the more stringent of either the applicable TBELS or the WQBELS in Pennsylvania's program (at Chapters 91–96), including the iron and manganese criteria for aquatic life and PWS use protection in Chapter 93, *Water Quality Standards.*

Regarding passive treatment systems, Pennsylvania clarified that the three subsets of discharges with defining criteria allowing for the use of passive treatment are a starting point and are not a substitute for actual performance of the passive treatment system. Pennsylvania stated the discharges must also meet in-stream numeric criteria for iron and manganese established in Chapter 93. Pennsylvania also mentioned that in addition to establishing TBELS for post-mining pollutional discharges, 25 Pa. Code § 87.102(e) prescribes design and construction requirements for passive treatment systems that Pennsylvania determined would be necessary to adequately treat the identified subset of post-mining pollutional discharges. Further, it stated that this section and its counterpart sections supplement existing NPDES requirements and are not intended to implement the NPDES regulations for case-by-case development of TBELS requirements in permits.

Pennsylvania responded to EPA's request for clarification of the definitions of *passive treatment* system and *post-mining pollutional discharge* by clarifying that passive treatment systems require ongoing operation and maintenance activity, but less frequent monitoring and continuous management; and that a post-mining pollutional discharge is a discharge emanating from, or hydrologically connected to, the permit area which remains after coal mining activities have been completed and does not meet effluent requirements in 25 Pa Code § 87.102 or its parallel counterparts.

Regarding EPA's concerns about NPDES permit modifications, Pennsylvania emphasized that PA SMCRA explicitly requires compliance with the regulations in Chapter 92a related to NPDES permitting and Chapter 93 related to water quality standards.

Pennsylvania acknowledged that its BPJ guidance was finalized in 1994 and that advances have been made over the past two decades but stated its staff is aware of technological improvements and has been applying this knowledge in practice for many years at specific sites.

OSMRE submitted Pennsylvania's December 9, 2011, letter to EPA for review and response on January 4, 2012 (Administrative Record No. PA 854.13).

2. *EPA 's Second Letter to OSMRE:* EPA responded to Pennsylvania's December 9, 2011, letter by sending us a letter dated August 20, 2013 (Administrative Record No. PA 854.15). EPA noted Pennsylvania's responses and provided its concurrence based on Pennsylvania's assertion that the more stringent of either TBELS or WQBELS will be used to determine the appropriate discharge limit from all outfalls subject to the referenced proposed revision. EPA also noted that its concurrence is contingent on Pennsylvania's assertion that Pennsylvania will not be using passive treatment regulatory standards for discharges emanating from underground mining operations. EPA recommended that Pennsylvania review its BPJ guidance for this proposed set of regulations and modify the guidance with any new information (including EPA's Acid Mine Drainage program implementation guidance) gained from studies performed by Pennsylvania and OSMRE.

3. *OSMRE's Third Letter to EPA:* By letter dated January 20, 2014, (Administrative Record No. PA 854.16), we sought clarification from EPA regarding several issues and comments submitted during the public comment period. The issues involved: Clarification regarding a January 28, 1992, Memorandum from EPA to Pennsylvania that concluded post-mining ground water seeps from reclaimed surface mines are not subject to the requirements of 40 CFR 434.52(a) (ELGS for post-mining areas); clarification from EPA regarding a public comment that EPA must first, or simultaneously, approve the changes in Pennsylvania's NPDES program; additional direction from EPA regarding use of the 1994 BPJ analysis for post-mining pollutional discharges; information regarding application of

WQBELS for streams not designated as a PWS; and information regarding application of provisions of the CWA that protect the biological integrity of receiving streams from chemical or organic constituents of water discharged.

4. *EPA 's Third Letter to OSMRE:* EPA responded to our letter of January 20, 2014, by sending us a letter dated May 20, 2014 (Administrative Record No. PA 854.17). In response to the issues and concerns identified in our January 20, 2014, letter, EPA responded with the following explanation:

Regarding EPA's position as presented in the January 28, 1992, Memorandum to Pennsylvania regarding treatment of post-mining discharges, EPA stated the position taken by EPA in 1992 does not reflect current EPA regulatory analysis. EPA responded that seepage at a reclamation site (surface mine in stage 2 reclamation) *does* (emphasis added) include water that drains through waste rock, overburden, etc., rather than flows over the surface, and these seepages are subject to the effluent limit guidelines in 434 Subchapter E, *Post-mining Areas.*

Responding to a public comment that EPA must approve the proposed revisions as part of a revision to Pennsylvania's NPDES program, EPA requested that OSMRE identify those sections of the Pennsylvania program for which this would be necessary. Regarding Pennsylvania's use of 1994 BPJ information, EPA responded that it was, at the time, in discussions with Pennsylvania regarding its BPJ process.

Regarding in-stream manganese WQBELS, EPA stated that in Pennsylvania, all streams are designated as PWS critical use and that, pursuant to 25 Pa. Code § 96.3(c), manganese is a PWS standard. According to this letter, compliance must be evaluated at the nearest downstream drinking water intake from the discharge. As noted in EPA's fourth letter to OSMRE, however, this statement is erroneous.

Regarding the protection of the biological integrity of receiving streams, EPA noted that under 40 CFR 122.44(d)(1)(ii), WET testing can and should be used to ensure discharges are not toxic and dangerous to aquatic life. EPA also noted 25 Pa. Code § 93.6, which states in part, that, ''[w]ater may not contain substances attributable to point or nonpoint source discharges in concentration or amounts sufficient to be inimical or harmful to the water uses to be protected or to human, animal, plant or aquatic life.''

5. *EPA 's Fourth Letter to OSMRE:* EPA sent us a letter on July 2, 2014, (Administrative Record No. PA 854.18), to correct a response that was given by EPA in its May 20, 2014, letter to us that addressed WQBELS for manganese in streams that are not designated PWS, critical use. EPA stated that, contrary to what it said in its May 20, 2014, letter, manganese is monitored at the point of discharge, rather than at the nearest downstream drinking water intake from the discharge.

6. *OSMRE's First Letter to Pennsylvania:* By letter dated August 7, 2014, (Administrative Record No. PA 854.20), we requested additional information from Pennsylvania and notified Pennsylvania of EPA's change in interpretation regarding ground water seeps and the applicability of the limitations provided in 40 CFR part 434. We questioned Pennsylvania on its position of including 25 Pa. Code § 87.102(e)(2)(iii), which is the third criterion involving permitted use of passive treatment for post-mining pollutional discharges involving a discharge with a net acidity always less than 300 mg/L, as a discharge criterion that is suitable for passive treatment. Further, we questioned the inclusion of the phrase ''but are not limited to'' in 25 Pa. Code § 87.102(e)(2) because it would allow approval of the use of passive treatment on other discharges not specified. We also noted the passage of 20 years since the BPJ analysis was issued and the emergence of more recent studies and other more recent experience demonstrating the limitations of passive treatment technologies. We questioned how the provisions of 25 Pa. Code §§ 87.102(e)(3) and (4) would be enforced; how the reclamation needs will be bonded or otherwise financially secured; and who would be responsible for operation and maintenance of the treatment systems. We also noted that Pennsylvania's regulations do not address the 40 CFR 434.52 effluent requirement that the discharge have no more than 0.5 ml/L of settleable solids.

7. *Pennsylvania's Second Letter to OSMRE:* Pennsylvania responded to our August 2014, letter on October 9, 2014, (Administrative Record No. 854.21), with the following responses:

Regarding our concern with the third category of discharges suitable for passive treatment (less than 300 mg/L of acidity) and the open-ended nature of the regulation that could lead to approval of passive treatment systems that cannot maintain effectiveness, Pennsylvania responded that the totality of the regulations prevents approval of a system that will not function well. Further, Pennsylvania asserted that only those passive treatment systems that can achieve the effluent requirements and can be designed and constructed to meet the performance requirements can be approved by Pennsylvania.

Pennsylvania asserted that 25 Pa. Code § 87.102(e)(3) and comparable sections in the other chapters are performance standards which must be met, and effluent limits will be determined and included in the NPDES permit that accompanies the SMCRA permit. Both the NPDES and SMCRA permits will be maintained as long as the post-mining pollutional discharge continues to require treatment. Pennsylvania advised that treatment systems will be bonded or otherwise financially secured in accordance with the approved program.

Pennsylvania asserted that there are no Federal counterparts to the provisions in 25 Pa. Code § 87.102(e) and comparable subsections, and, therefore, they are as effective as and no less stringent than the Federal requirements. Pennsylvania asserted it uses all the tools available in its technical review to ensure treatment of post-mining pollutional discharges is consistent with current scientific knowledge and uses the best system of performance.

Regarding our concerns about the absence of a settleable solids limit in the Pennsylvania regulations for post-mining pollutional discharges, and recognizing that the EPA standards at 40 CFR 434.52(a) for post-mining areas require no more than 0.5 ml/L in the discharge, Pennsylvania responded that the narrative water quality standards at 25 Pa. Code 93.6(b), Water quality criteria, addresses pollutants, turbidity, or settle-to-form deposits. Pennsylvania stated turbidity addresses suspended solids, while settle-to-form deposits address settleable solids and that NPDES permits for individual coal mining permits will properly address settleable solids.

Regarding system performance monitoring and maintenance, Pennsylvania responded that the operator is responsible for compliance with the monitoring schedule in the NPDES permit and for operation and maintenance of the treatment systems.

Regarding financial assurances for reclamation needs, Pennsylvania stated that the treatment systems will become part of the SMCRA and NPDES permits and will be bonded in accordance with financial assurance requirements approved by OSMRE on August 10, 2010. (78 FR 48526).

8. *EPA 's Fifth Letter to OSMRE:* On March 26, 2015, (Administrative Record No. PA 854.22), EPA sent us a letter referencing its August 20, 2013, concurrence letter and its January 20, 2014, follow-up letter. It reiterated its

conditional concurrence that made clear its approval is contingent upon Pennsylvania's assertion that the more stringent of either TBELS or WQBELS will apply to any NPDES discharge regardless of SMCRA obligations; that the provisions of 30 CFR 816.42, requiring that all applicable State and Federal water quality laws and regulations along with EPA effluent limitations in 40 CFR part 434 will apply; and neither SMCRA nor its implementing regulations supersede, modify, or repeal the CWA and its implementing regulations. EPA also stated that NPDES permits for post-mining pollutional discharges require the pH to be between 6.0 and 9.0 unless there is a variance and require that settleable solids not exceed 0.5 mg/L.

V. OSMRE's Decision

Based on the above findings, we are approving the Pennsylvania amendment that was sent to us on October 1, 2010, with one exception. We are deferring our decision on the inclusion of minimal impact post-mining discharges in the definition of *post-mining pollutional discharge* until such time as the State submits the definition of *minimal impact post-mining discharge* to us as a proposed program amendment.

To implement this decision, we are amending the Federal regulations, at 30 CFR part 938, that codify decisions concerning the Pennsylvania program. In accordance with the Administrative Procedure Act (5 U.S.C. 500 *et seq.*), this rule will take effect 30 days after the date of publication. Section 503(a) of SMCRA requires that the State's program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. SMCRA requires consistency of State and Federal standards.

VI. Statutory and Executive Order Reviews

Executive Order 12630—Governmental Actions and Interference With Constitutionality Protected Property Rights

This rule would not effect a taking of private property or otherwise have taking implications that would result in public property being taken for government use without just compensation under the law. Therefore, a takings implication assessment is not required. This determination is based on an analysis of the corresponding Federal regulations.

Executive Order 12866—Regulatory Planning and Review and 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993, the approval of State program amendments is exempted from OMB review under Executive Order 12866. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Executive Order 13771—Reducing Regulation and Controlling Regulatory Costs

State program amendments are not regulatory actions under Executive Order 13771 because they are exempt from review under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has reviewed this rule as required by section 3(a) of Executive Order 12988. The Department has determined that this **Federal Register** notice meets the criteria of section 3 of Executive Order 12988, which is intended to ensure that the agency review its legislation and proposed regulations to eliminate drafting errors and ambiguity; that the agency write its legislation and regulations to minimize litigation; and that the agency's legislation and regulations provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. Because section 3 focuses on the quality of Federal legislation and regulations, the Department limited its review under this Executive Order to the quality of this **Federal Register** notice and to changes to the Federal regulations. The review under this Executive Order did not extend to the language of the State regulatory program or to the program amendment that the Commonwealth of Pennsylvania drafted.

Executive Order 13132—Federalism

This rule has potential Federalism implications as defined under Section 1(a) of Executive Order 13132. Executive Order 13132 directs agencies to ''grant the States the maximum administrative discretion possible'' with respect to Federal statutes and regulations administered by the States. Pennsylvania, through its approved regulatory program, implements and administers SMCRA and its implementing regulations at the state level. This rule approves an amendment to the Pennsylvania program submitted and drafted by the State, and thus is consistent with the direction to provide maximum administrative discretion to States.

Executive Order 13175—Consultation and Coordination With Indian Tribal Government

The Department of the Interior strives to strengthen its government-to-government relationship with Tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and tribal sovereignty. 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 no substantial direct effects on federally recognized Tribes or on the distribution of power and responsibilities between the Federal Government and Tribes. Therefore, consultation under the Department's tribal consultation policy is not required. The basis for this determination is that our decision is on the Pennsylvania program that does not include Tribal lands or regulation of activities on Tribal lands. Tribal lands are regulated independently under the applicable, approved Federal program.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211 requires agencies to prepare a Statement of Energy Effects for a rulemaking that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not significant energy action under the definition in Executive Order 13211, a Statement of Energy Effects is not required.

Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks

This rule is not subject to Executive Order 13045 because this is not an economically significant regulatory action as defined by Executive Order 12866; and this action does not address environmental health or safety risks disproportionately affecting children.

National Environmental Policy Act

Consistent with sections 501(a) and 702(d) of SMCRA (30 U.S.C. 1251 (a) and 1292(d), respectively) and the U.S. Department of the Interior Departmental

Manual, part 516, section 13.5(A), State program amendments are not major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C).

National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (15 U.S.C. 3701 *et seq.*) directs OSMRE to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. (OMB Circular A–119 at p. 14). This action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with SMCRA.

Paperwork Reduction Act

This rule does not include requests and requirements of an individual, partnership, or corporation to obtain information and report it to a Federal agency. As this rule does not contain information collection requirements, a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required.

Regulatory Flexibility Act

This rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (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. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to constitute a major rule.

Unfunded Mandates Reform Act

This rule will not impose an unfunded mandate on State, local, or Tribal governments, or the private sector of more than $100 million in any given year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. This determination is based an analysis of the corresponding Federal regulations, which were determined not to impose an unfunded mandate. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Thomas D. Shope,

Regional Director, North Atlantic—Appalachian Region.

For the reasons set out in the preamble, the Office of Surface Mining Reclamation and Enforcement amends 30 CFR part 938 as follows:

PART 938—PENNSYLVANIA

■ 1. The authority citation for part 938 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 938.12 is amended by adding paragraph (f):

§ 938.12 State regulatory program and proposed program amendment provisions not approved.

* * * * *

(f) We are deferring our decision on the inclusion of *minimal-impact post-mining discharge* in the definition of *post-mining pollutional discharge* until such time as the State submits the definition of minimal-impact post-mining discharge to us as a proposed program amendment.

■ 3. In § 938.15 amend the table by adding under ''Date of Final Publication'' an entry for ''Section 4.2(j) of PASMCRA (52 P.S. § 1396.4bG)) at the end of the table to read as follows

§ 938.15 Approval of Pennsylvania regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
*	*	*
October 1, 2010	November 9, 2020	Section 4.2(j) of PASMCRA 52 P.S. § 1396.4bj); 25 Pa. Code § 86.1, Definitions, the definitions of the following terms: ''passive treatment system'' and ''post-mining pollutional discharge, except for the inclusion of ''minimal impact post-mining discharge'' in the definition of ''post-mining pollutional discharge'' 25 Pa Code 87.102(a) and (e), Hydrologic balance: Effluent standards; 88.92 (a) and (e); Hydrologic balance: Effluent standards; 88.187 (a) and (e), Hydrologic balance: Effluent standards; 88.292 (a) and (e), Hydrologic balance: Effluent standards; 89.52 (c), Water quality standards, effluent limitations, and best management practices; and 90.102 (a) and (e), Hydrologic balance: Water quality standards, effluent limitations, and best management practices.

[FR Doc. 2020–23215 Filed 11–6–20; 8:45 am]

BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R09–OAR–2019–0145; FRL–10015–43–Region 9]

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; California; South Coast Moderate Area Plan and Reclassification as Serious Nonattainment for the 2012 $PM_{2.5}$ NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve or conditionally approve portions of a state implementation plan (SIP) revision submitted by California to address Clean Air Act (CAA or ''Act'') requirements for the 2006 and 2012 fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS or ''standards'') in the Los Angeles-South Coast Air Basin (''South Coast'') $PM_{2.5}$ nonattainment area. Specifically, the EPA is approving all but the contingency measure element of the submitted SIP revision as meeting all applicable Moderate area requirements for the 2012 annual $PM_{2.5}$ NAAQS, and conditionally approving the contingency measure element as meeting both the Moderate area contingency measure requirement for the 2012 annual $PM_{2.5}$ NAAQS and the Serious area contingency measure requirement for the 2006 24-hour $PM_{2.5}$ NAAQS. In addition, the EPA is approving 2019 and 2022 motor vehicle emissions budgets for use in transportation conformity analyses for the 2012 annual $PM_{2.5}$ NAAQS. The EPA is also reclassifying the South Coast $PM_{2.5}$ nonattainment area, including reservation areas of Indian country and any other area of Indian country within it where the EPA or a tribe has demonstrated that the tribe has jurisdiction, as a Serious nonattainment area for the 2012 annual $PM_{2.5}$ NAAQS based on the EPA's determination that the area cannot practicably attain the standard by the applicable Moderate area attainment date of December 31, 2021. As a consequence of this reclassification, California is required to submit a Serious area attainment plan that includes a demonstration of attainment of the 2012 annual $PM_{2.5}$ NAAQS in the South Coast area as expeditiously as practicable and no later than December 31, 2025.

DATES: This rule will be effective on December 9, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2019–0145. 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.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ashley Graham, Air Planning Office (AIR–2), EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 972–3877, or by email at *graham.ashleyr@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Background

Epidemiological studies have shown statistically significant correlations between elevated levels of $PM_{2.5}$ (particulate matter with a diameter of 2.5 microns or less) and premature mortality. Other important health effects associated with $PM_{2.5}$ exposure include aggravation of respiratory and cardiovascular disease, changes in lung function, and increased respiratory symptoms. Individuals particularly sensitive to $PM_{2.5}$ exposure include older adults, people with heart and lung disease, and children.[1] $PM_{2.5}$ can be emitted directly into the atmosphere as a solid or liquid particle (''primary $PM_{2.5}$'' or ''direct $PM_{2.5}$'') or can be formed in the atmosphere as a result of various chemical reactions among precursor pollutants such as nitrogen oxides, sulfur oxides, volatile organic compounds, and ammonia (''secondary $PM_{2.5}$'').[2]

The EPA first established annual and 24-hour NAAQS for $PM_{2.5}$ on July 18, 1997.[3] The annual standard was set at 15.0 micrograms per cubic meter (μg/m^3) based on a 3-year average of annual mean $PM_{2.5}$ concentrations, and the 24-hour (daily) standard was set at 65 μg/m^3 based on the 3-year average of the annual 98th percentile values of 24-hour $PM_{2.5}$ concentrations at each monitor within an area.[4] On October 17, 2006, the EPA revised the level of the 24-hour $PM_{2.5}$ NAAQS to 35 μg/m^3 based on a 3-year average of the annual 98th percentile values of 24-hour concentrations.[5] On January 15, 2013, the EPA revised the annual standard to 12.0 μg/m^3 based on a 3-year average of annual mean $PM_{2.5}$ concentrations.[6] We refer to this standard as the 2012 $PM_{2.5}$ NAAQS.

Following promulgation of a new or revised NAAQS, the EPA is required by CAA section 107(d) to designate areas throughout the nation as attaining or not attaining the NAAQS. On November 13, 2009, the EPA designated the South Coast area as nonattainment for the 2006 $PM_{2.5}$ NAAQS.[7] The EPA classified the area as Moderate nonattainment on June 2, 2014 and reclassified it as Serious nonattainment for these NAAQS on January 13, 2016.[8] On January 15, 2015, the EPA designated and classified the South Coast area as Moderate nonattainment for the 2012 $PM_{2.5}$ NAAQS.[9] The South Coast area is also designated and classified as Moderate

[1] 78 FR 3086, 3088 (January 15, 2013).

[2] EPA, Air Quality Criteria for Particulate Matter, No. EPA/600/P–99/002aF and EPA/600/P–99/002bF, October 2004.

[3] 62 FR 38652 (codified at 40 CFR 50.7).

[4] The primary and secondary standards were set at the same level for both the 24-hour and the annual $PM_{2.5}$ standards.

[5] 71 FR 61144.

[6] 78 FR 3086.

[7] 74 FR 58688 (codified at 40 CFR 81.305).

[8] 79 FR 31566 and 81 FR 1514. The EPA promulgated these $PM_{2.5}$ nonattainment area classifications in response to a 2013 decision of the Court of Appeals for the D.C. Circuit remanding the EPA's prior implementation rule for the $PM_{2.5}$ NAAQS and directing the EPA to promulgate implementation rules pursuant to subpart 4 of part D, title I of the Act. *Natural Resources Defense Council* v. *EPA,* 706 F.3d 428 (D.C. Cir. 2013).

[9] 80 FR 2206 (codified at 40 CFR 81.305).

nonattainment for the 1997 annual and 24-hour $PM_{2.5}$ NAAQS.[10]

The local air district with primary responsibility for developing a plan to attain the $PM_{2.5}$ NAAQS in the South Coast area is the South Coast Air Quality Management District (SCAQMD or ''District''). The District works cooperatively with the California Air Resources Board (CARB) in preparing these plans. Authority for regulating sources in the South Coast is split between the District, which has responsibility for regulating stationary and most area sources, and CARB, which has responsibility for regulating most mobile sources and some categories of consumer products.

On July 2, 2020, we proposed to approve or conditionally approve portions of a SIP revision submitted by California to address CAA requirements for the $PM_{2.5}$ NAAQS in the South Coast nonattainment area.[11] The submitted SIP revision, the ''Final 2016 Air Quality Management Plan (March 2017),'' was adopted by the SCAQMD Governing Board on March 3, 2017 and submitted by CARB to the EPA on April 27, 2017.[12] We refer to those portions of this SIP submission that address the Serious area requirements for the 2006 $PM_{2.5}$ NAAQS and the Moderate area requirements for the 2012 $PM_{2.5}$ NAAQS as the ''2016 $PM_{2.5}$ Plan'' or ''Plan.'' The EPA previously approved those portions of the 2016 $PM_{2.5}$ Plan that pertain to the requirements for implementing the 2006 $PM_{2.5}$ NAAQS, except for the contingency measure component of the Plan.[13]

As part of our July 2, 2020 action, we proposed to approve the following elements of the 2016 $PM_{2.5}$ Plan as meeting the CAA Moderate area requirements for the 2012 $PM_{2.5}$ NAAQS: The 2012 base year emissions inventories, the reasonably available control measure/reasonably available control technology (RACM/RACT) demonstration, the demonstration that attainment by the Moderate area attainment date of December 31, 2021 is impracticable, the reasonable further progress (RFP) demonstration, the quantitative milestones, the motor vehicle emissions budgets for 2019 and 2022, and SCAQMD's commitments to adopt and implement specific rules and measures to achieve emission reductions and to submit the rules and measures to CARB for transmittal to the EPA as a revision to the SIP. We also proposed to conditionally approve the contingency measure element of the 2016 $PM_{2.5}$ Plan as meeting the Serious area planning requirements for the 2006 $PM_{2.5}$ NAAQS and the Moderate area planning requirements for the 2012 $PM_{2.5}$ NAAQS. Lastly, we proposed to reclassify the South Coast $PM_{2.5}$ nonattainment area, including reservation areas of Indian country, as Serious nonattainment for the 2012 $PM_{2.5}$ standard.[14]

With respect to the contingency measure requirement, in our proposed rule, we noted that the EPA's longstanding interpretation of section 172(c)(9) that states may rely on already-implemented measures as contingency measures (if they provide emissions reductions in excess of those needed to meet any other nonattainment plan requirements) was rejected by the Ninth Circuit Court of Appeals in a case referred to as *Bahr* v. *EPA* (''*Bahr*'').[15] In *Bahr,* the Ninth Circuit concluded that contingency measures must be measures that would take effect at the time the area fails to make RFP or to attain by the applicable attainment date, not before.[16] Thus, within the geographic jurisdiction of the Ninth Circuit, states cannot rely on already-implemented control measures to comply with the contingency measure requirements under CAA sections 172(c)(9).

Our proposed conditional approval of the contingency measure element of the 2016 $PM_{2.5}$ Plan relied on specific commitments: (1) From the District to modify an existing rule, Rule 445 (''Wood Burning Devices''), to lower the wood burning curtailment threshold upon any of the four EPA determinations (*i.e.,* ''findings of failure'') listed in 40 CFR 51.1014(a); (2) from the District to submit the revised rule to CARB for transmittal to the EPA by the earlier of (a) one year from the date of the EPA's conditional approval of the contingency measures for the 2012 annual $PM_{2.5}$ standard, or (b) 60 days after the date the EPA makes a determination that the South Coast area has failed to attain the 2006 24-hour $PM_{2.5}$ standards but no later than one year after the date of the EPA's conditional approval of the contingency measures for these standards;[17] and (3) from CARB to submit the revised District rule to the EPA as a SIP revision by the earlier of these two dates.[18] For more information about these submittals, please see our proposed rule.

With respect to reclassification, in the proposed rule, we explained that under section 188(c)(2) of the Act, the attainment date for a Serious area ''shall be as expeditiously as practicable but no later than the end of the tenth calendar year beginning after the area's designation as nonattainment. . .'' The EPA designated the South Coast area as nonattainment for the 2012 $PM_{2.5}$ standard effective April 15, 2015.[19] Therefore, as a result of our reclassification of the South Coast area as a Serious nonattainment area, the attainment date under section 188(c)(2) of the Act for the 2012 $PM_{2.5}$ NAAQS in this area is as expeditiously as practicable but no later than December 31, 2025.

Our proposed rule also identified the Serious area attainment plan elements that California would, upon reclassification, have to submit to satisfy the statutory requirements that apply to Serious areas, including the requirements of subpart 4 of part D, title I of the Act.[20] The EPA explained that under section 189(b)(2) of the Act, the State must submit the required provisions to implement best available control measures (BACM), including best available control technology (BACT),[21] no later than 18 months after

[10] 70 FR 944 (January 5, 2005) (codified at 40 CFR 81.305). In November 2007, California submitted the 2007 $PM_{2.5}$ Plan to provide for attainment of the 1997 $PM_{2.5}$ standards in the South Coast. On November 9, 2011, the EPA approved all but the contingency measures in the 2007 $PM_{2.5}$ Plan (76 FR 69928), and on October 29, 2013, the EPA approved a revised contingency measure SIP for the area (78 FR 64402). On July 25, 2016, the EPA determined that the South Coast area had attained the 1997 annual and 24-hour $PM_{2.5}$ NAAQS based on 2011–2013 monitoring data, suspending any remaining attainment-related planning requirements for purposes of the 1997 $PM_{2.5}$ NAAQS in this area (81 FR 48350).

[11] 85 FR 40026.

[12] Letter dated April 27, 2017, from Richard Corey, Executive Officer, CARB, to Alexis Strauss, Acting Regional Administrator, EPA Region IX, with enclosures.

[13] 84 FR 3305 (February 12, 2019). As part of this action, the EPA found that, for purposes of the 2006 $PM_{2.5}$ NAAQS, the requirement for contingency measures to be undertaken if the area fails to make RFP under CAA sections 172(c)(9) was moot as applied to the 2017 milestone year because CARB and the District had demonstrated to the EPA's satisfaction that the 2017 milestones in the plan had been met. The EPA took no action with respect to the RFP contingency measures for the 2020 milestone year or attainment contingency measures for these NAAQS.

[14] 85 FR 40026.

[15] *Bahr* v. *EPA,* 836 F. 3d 1218, 1235–1237 (9th Cir. 2016).

[16] Id. at 1235–1237.

[17] Letter dated February 12, 2020, from Wayne Nastri, Executive Officer, SCAQMD, to Richard Corey, Executive Officer, CARB.

[18] Letter dated March 3, 2020, from Michael T. Benjamin, Chief, Air Quality Planning and Science Division, CARB, to Amy Zimpfer, Associate Director, Air Division, EPA Region IX (transmitting letter dated February 12, 2020, from Wayne Nastri, Executive Officer, SCAQMD, to Richard Corey, Executive Officer, CARB).

[19] 80 FR 2206 (codified at 40 CFR 81.305).

[20] 85 FR 40026.

[21] The EPA defines BACM as, among other things, the maximum degree of emissions reduction

Continued

reclassification. Because an up-to-date emissions inventory serves as the foundation for a state's BACM and BACT determinations, the EPA proposed to also require the State to submit the emissions inventory required under CAA section 172(c)(3) within 18 months after the effective date of final reclassification. Similarly, because an effective evaluation of BACM and BACT requires evaluation of the precursor pollutants that must be controlled to provide for expeditious attainment in the area, the EPA proposed to require the State to submit any optional precursor insignificance demonstrations by this same date. The EPA proposed to require the State to submit the attainment demonstration required under section 189(b)(1)(A) and all other attainment-related plan elements for the South Coast area no later the end of the eighth calendar year after designation—*i.e.,* by December 31, 2023. We noted that although section 189(b)(2) generally provides for up to four years after a discretionary reclassification for the state to submit the required attainment demonstration, given the timing of the reclassification action less than two years before the Moderate area attainment date, it is appropriate in this case for the EPA to establish an earlier SIP submission deadline to assure timely implementation of the statutory requirements.[22]

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period that ended on August 3, 2020. During this period, the EPA received comments from three anonymous commenters.[23] None of the comments received are relevant to the EPA's action.

III. Final Action

A. Moderate Area Planning Requirements

For the reasons discussed in detail in the proposed rule and summarized herein, under CAA section 110(k)(3), the EPA is taking final action to approve or conditionally approve portions of the 2016 $PM_{2.5}$ Plan submitted by the State of California. We are finalizing approval of the following elements of the 2016 $PM_{2.5}$ Plan as meeting the Moderate area requirements for the 2012 $PM_{2.5}$ NAAQS:

- The base year emissions inventories as meeting the requirements of CAA section 172(c)(3);
- the RACM/RACT demonstration as meeting the requirements of CAA sections 172(c)(1) and 189(a)(1)(C);
- the demonstration that attainment by the Moderate area attainment date of December 31, 2021 is impracticable as meeting the requirements of CAA section 189(a)(1)(B)(ii);
- the RFP demonstration as meeting the requirements of CAA section 172(c)(2);
- the quantitative milestones as meeting the requirements of CAA section 189(c);
- the motor vehicle emissions budgets for 2019 and 2022, because they are derived from an approvable RFP demonstration and meet the requirements of CAA section 176(c) and 40 CFR part 93, subpart A;[24] and
- the SCAQMD's commitments to adopt and implement specific rules and measures in accordance with the schedule provided in Chapter 4 of the 2016 $PM_{2.5}$ Plan to achieve the emission reductions shown therein, and to submit these rules and measures to CARB for transmittal to the EPA as a revision to the SIP, as stated on page 9 of SCAQMD Governing Board Resolution 17–2.

The EPA is also finalizing a conditional approval of the contingency measure element of the 2016 $PM_{2.5}$ Plan as meeting the requirements of CAA section 172(c)(9) for the 2006 $PM_{2.5}$ NAAQS and for the 2012 $PM_{2.5}$ NAAQS. We note that the EPA determined on September 16, 2020, that the South Coast area had failed to timely attain the 2006 $PM_{2.5}$ NAAQS,[25] and that CARB is required to submit specified revisions to Rule 445 (''Wood Burning Devices'') as a SIP revision to the EPA no later than 60 days after this date, consistent with the terms of its commitment under CAA section 110(k)(4).[26]

B. Reclassification as Serious Nonattainment and Applicable Attainment Date

In accordance with section 188(b)(1) of the Act, the EPA is taking final action to reclassify the South Coast area from Moderate to Serious nonattainment for the 2012 annual $PM_{2.5}$ standard, based on the agency's determination that the South Coast area cannot practicably attain the standard by the Moderate area attainment date of December 31, 2021.

Under section 188(c)(2) of the Act, the attainment date for a Serious area ''shall be as expeditiously as practicable but no later than the end of the tenth calendar year beginning after the area's designation as nonattainment . . .'' The South Coast area was designated nonattainment for the 2012 $PM_{2.5}$ NAAQS effective April 15, 2015.[27] Therefore, as a result of our reclassification of the South Coast area as a Serious nonattainment area, section 188(c)(2) of the Act requires that the area attain the 2012 $PM_{2.5}$ NAAQS as expeditiously as practicable but no later than December 31, 2025.

C. Reclassification of Reservation Areas of Indian Country

When the South Coast area was designated nonattainment for the 2012 $PM_{2.5}$ NAAQS, five Indian tribes were located within the boundaries of the nonattainment area: The Cahuilla Band of Mission Indians of the Cahuilla Reservation, the Morongo Band of Mission Indians, the Ramona Band of Cahuilla, the San Manuel Band of Mission Indians, and the Soboba Band of Luiseno Indians. At that time, the main body of land belonging to the Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation was expressly excluded from the South Coast 2012 $PM_{2.5}$ nonattainment area. However, since designation, the tribe has acquired the Meadowbrook parcel, which is located approximately 30 miles northwest of the northern boundary of the Reservation and is located within the South Coast $PM_{2.5}$ nonattainment area.[28]

achievable for a source or source category, which is determined on a case-by-case basis considering energy, environmental, and economic impacts. 59 FR 41998, 42010 and 42014 (August 16, 1994). BACM must be implemented for all categories of sources in a Serious $PM_{2.5}$ nonattainment area unless the state adequately demonstrates that a particular source category does not contribute significantly to nonattainment of the $PM_{2.5}$ standard. Id. at 42011–42012.

[22] Id. at 40054–40055.

[23] The docket for this rulemaking contains these comment letters, with the exception of sixteen attachments to one comment letter that contain copyright and trademark claims. The EPA did not receive any comments regarding the impact of the Safer Affordable Fuel Efficient (SAFE) actions (84 FR 51310 (September 27, 2019) and 85 FR 24174 (April 30, 2020)) on the South Coast 2016 $PM_{2.5}$ Plan.

[24] In our July 2, 2020 action, we proposed to limit the duration of our approval of the budgets in the 2016 $PM_{2.5}$ Plan to the period before the effective date of the EPA's adequacy finding for any subsequently submitted budgets per a request from CARB (85 FR 40026, 40053). We did not receive any comments on our proposal to limit the duration of the budgets and are finalizing our approval of the budgets for this limited period, as proposed.

[25] 85 FR 57733 (September 16, 2020).

[26] Letter dated March 3, 2020, from Michael T. Benjamin, Chief, Air Quality Planning and Science Division, CARB, to Amy Zimpfer, Associate Director, Air Division, EPA Region IX (transmitting letter dated February 12, 2020, from Wayne Nastri, Executive Officer, SCAQMD, to Richard Corey, Executive Officer, CARB).

[27] 80 FR 2206 (codified at 40 CFR 81.305).

[28] 85 FR 40026, 40055.

We have considered the relevance of our final action to reclassify the South Coast area as Serious nonattainment for the 2012 $PM_{2.5}$ standard for each tribe located within the South Coast area. As discussed in more detail in our proposed rule, we believe that the same facts and circumstances that support the reclassification for the non-Indian country lands also support reclassification for reservation areas of Indian country [29] and any other areas of Indian country where the EPA or a tribe has demonstrated that the tribe has jurisdiction located within the South Coast nonattainment area.[30] In this final action, the EPA is therefore exercising its authority under CAA section 188(b)(1) to reclassify reservation areas of Indian country and any other areas of Indian country where the EPA or a tribe has demonstrated that the tribe has jurisdiction geographically located in the South Coast nonattainment area. Section 188(b)(1) broadly authorizes the EPA to reclassify a nonattainment area—including any Indian country located within such an area—that the EPA determines cannot practicably attain the relevant standard by the applicable attainment date.

In light of the considerations outlined above and in our proposed rulemaking that support retention of a uniformly-classified $PM_{2.5}$ nonattainment area, and our finding that it is impracticable for the area to attain by the applicable attainment date, we are finalizing our reclassification of the reservation areas of Indian country and any other areas of Indian country where the EPA or a tribe has demonstrated that the tribe has jurisdiction within the South Coast nonattainment area to Serious for the 2012 $PM_{2.5}$ standard.

Generally, the effect of reclassification is to lower the applicable ''major source'' emissions thresholds for direct $PM_{2.5}$ and $PM_{2.5}$ precursors for purposes of the nonattainment new source review (NNSR) program and the Title V operating permit program from 100 tpy to 70 tpy,[31] thus subjecting more new or modified stationary sources to these requirements. Reclassification also lowers the de minimis threshold under the CAA's General Conformity requirements from 100 tpy to 70 tpy.[32] In this case, however, reclassification does not change the ''major source'' thresholds because, as a result of the EPA's January 2016 reclassification of the South Coast area as a ''Serious'' nonattainment area for the 2006 $PM_{2.5}$ NAAQS, the area is already subject to the 70 tpy major source threshold for Serious $PM_{2.5}$ nonattainment areas in CAA section 189(b)(3).[33] Likewise, reclassification does not affect the applicable General Conformity de minimis thresholds, because the South Coast area is already subject to the 70 tpy de minimis threshold for $PM_{2.5}$ and all $PM_{2.5}$ precursors as a result of the EPA's previous reclassification of the area as Serious for the 2006 $PM_{2.5}$ NAAQS.[34]

The EPA contacted tribal officials early in the process of developing this action to provide time for tribal officials to have meaningful and timely input into its development.[35] On March 12, 2020, during two separate conference calls, the EPA participated in formal consultation with the Morongo Band of Mission Indians and staff-level consultation with the Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, following requests from these tribes. During these calls, EPA staff presented information about the nonattainment designation for the 2012 $PM_{2.5}$ NAAQS in the South Coast area and about the SCAQMD's request, and EPA and tribal representatives together discussed the tribe's questions about the implications of the request for each tribe. At the close of each call, the tribes indicated that they had no further questions and the Morongo Band of Mission Indians later requested that the EPA close formal consultation. On April 30, 2020, the EPA sent a letter to the Morongo Band of Mission Indians closing formal consultation.[36] No other Indian tribe has expressed an interest in discussing this action with the EPA. A summary of the tribal consultation is included in the docket for this action.[37]

We notified tribal officials when the proposed action published in the **Federal Register** and continue to invite Indian tribes in the South Coast to contact the EPA with any questions about the effects of this reclassification on tribal interests and air quality. We note that although eligible tribes may seek EPA approval of relevant tribal programs under the CAA, none of the affected tribes will be required to submit an implementation plan as a result of this reclassification.

D. $PM_{2.5}$ Serious Area SIP Requirements

As a consequence of our reclassification of the South Coast area as a Serious nonattainment area for the 2012 $PM_{2.5}$ NAAQS, California is required to submit additional SIP revisions to satisfy the statutory requirements that apply to Serious $PM_{2.5}$ nonattainment areas, including the requirements of subpart 4 of part D, title I of the Act.

The Serious area SIP elements for the 2012 $PM_{2.5}$ NAAQS that California is required to submit are as follows:

1. Provisions to assure that BACM, including BACT for stationary sources, for the control of direct $PM_{2.5}$ and $PM_{2.5}$ precursors shall be implemented no later than four years after the area is reclassified (CAA section 189(b)(1)(B));
2. A demonstration (including air quality modeling) that the plan provides for attainment as expeditiously as practicable but no later than December 31, 2025, or where the state is seeking an extension of the attainment date under section 188(e), a demonstration that attainment by December 31, 2025 is impracticable and that the plan provides for attainment by the most expeditious alternative date practicable and no later than December 31, 2030 (CAA sections 189(b)(1)(A), 188(c)(2), and 188(e));
3. Plan provisions that require RFP (CAA 172(c)(2));
4. Quantitative milestones that are to be achieved every three years until the area is redesignated attainment and that demonstrate RFP toward attainment by the applicable date (CAA section 189(c));
5. Provisions to assure that control requirements applicable to major stationary sources of $PM_{2.5}$ also apply to major stationary sources of $PM_{2.5}$ precursors, except where the state demonstrates to the EPA's satisfaction that such sources do not contribute significantly to $PM_{2.5}$ levels that exceed the standard in the area (CAA section 189(e));
6. A comprehensive, accurate, current inventory of actual emissions from all sources of $PM_{2.5}$ and all $PM_{2.5}$ precursors in the area (CAA 172(c)(3));

[29] ''Indian country'' as defined at 18 U.S.C. 1151 refers to: ''(a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state, and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.''

[30] 85 FR 40026, 40055–40056.

[31] CAA sections 189(b)(3) and 501(2)(B).

[32] 40 CFR part 93, subpart B.

[33] 81 FR 1514 (January 13, 2016).

[34] Id. and 40 CFR 93.153(b).

[35] As discussed in more detail in our proposed rule, the EPA sent letters to tribal officials inviting government-to-government consultation. These letters can be found in the docket.

[36] Letter dated April 30, 2020, from Elizabeth Adams, Director, Air and Radiation Division, EPA Region IX, to Robert Martin, Tribal Chairman, Morongo Band of Mission Indians.

[37] Memo dated April 14, 2020, from Ashley Graham, Air Planning Office, Air and Radiation Division, EPA Region IX, to Docket No. EPA–R09–OAR–2019–0145.

7. Contingency measures to be implemented if the area fails to meet RFP or to attain by the applicable attainment date (CAA section 172(c)(9)); and

8. A revision to the NNSR program to lower the applicable ''major stationary source'' [38] thresholds from 100 tpy to 70 tpy (CAA section 189(b)(3)) and to satisfy the subpart 4 control requirements for major stationary sources of $PM_{2.5}$ precursors (CAA section 189(e)).[39]

As discussed above in Section I, section 189(b)(2) of the CAA requires a state to submit the required BACM provisions no later than 18 months after the effective date of final reclassification. Because an effective BACM evaluation requires an up-to-date emissions inventory and an evaluation of the precursor pollutants that must be controlled to provide for expeditious attainment in the area, we are also requiring the State to submit the emissions inventory required under CAA section 172(c)(3) and any optional precursor insignificance demonstrations by this same date. Although section 189(b)(2) generally provides for up to four years after a discretionary reclassification for the state to submit the required attainment demonstration, given the timing of the reclassification action less than two years before the Moderate area attainment date, we are establishing a deadline of December 31, 2023 for the State to submit the attainment demonstration required under section 189(b)(1)(A) and all other attainment related plan elements for the South Coast area.

We note that the 2016 $PM_{2.5}$ Plan submitted on April 27, 2017, includes a Serious area attainment demonstration, an emissions inventory, attainment-related plan elements, and BACM/BACT provisions, which the EPA intends to evaluate and act on through subsequent rulemakings, as appropriate.

IV. Statutory and Executive Order Reviews

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 8, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Ammonia, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control, Particulate matter.

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

Dated: October 10, 2020.

John Busterud,

Regional Administrator, Region IX.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

[38] For any Serious area, the terms ''major source'' and ''major stationary source'' include any stationary source that emits or has the potential to emit at least 70 tpy of PM_{10} (CAA sections 189(b)(3)).

[39] As discussed in our proposed rule, California submitted NNSR SIP revisions for the South Coast to address the subpart 4 NNSR requirements for Serious $PM_{2.5}$ nonattainment areas on May 8, 2017, and the EPA conditionally approved these NNSR SIP revisions on November 30, 2018 (83 FR 61551). The State fulfilled the commitment that provided the basis for the EPA's conditional approval of these NNSR SIP revisions by submitting a revised version of Rule 1325 (''Federal $PM_{2.5}$ New Source Review Program'') on April 24, 2019.

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(517)(ii)(B)(*7*) to read as follows:

§ 52.220 Identification of plan—in part.

* * * * *

(c) * * *

(517) * * *

(ii) * * *

(B) * * *

(*7*) The following portions of the ''Final 2016 Air Quality Management Plan (March 2017),'' adopted March 3, 2017: Chapter 5 (''$PM_{2.5}$ Modeling Approach''), pages 5–17 through 5–27; Appendix III (''Base and Future Year Emission Inventory''), Attachment A (''Annual Average Emissions by Source Category in South Coast Air Basin'') for $PM_{2.5}$, NO_X, SO_2, VOC, and NH_3 for years 2012, 2019, 2021, and 2022, and Attachment D, tables D–1, D–7, D–11, and D–13; Appendix IV–A (''SCAQMD's Stationary and Mobile Source Control Measures''), Table IV–A–4 and Section 2 (''$PM_{2.5}$ Control Measures''); Appendix IV–C (''Regional Transportation Strategy and Control Measures''), Section III (''Reasonably Available Control Measure Analysis''); Appendix V (''Modeling and Attainment Demonstration''), Chapter 6 (''Annual $PM_{2.5}$ Attainment Demonstration'') and Attachment 7 (''Annual Unmonitored Area Analysis Supplement''); Appendix VI–A (''Reasonably Available Control Measures (RACM)/Best Available Control Measures (BACM) Demonstration''), pages VI–A–5 through VI–A–11, pages VI–A–22 through VI–A–32, pages VI–A–36 through VI–A–38, Attachment VI–A–1 (''Evaluation of SCAQMD Rules and Regulations''), Attachment VI–A–2 (''Control Measure Assessment''), and Attachment VI–A–3 (''California Mobile Source Control Program Best Available Control Measures/Reasonably Available Control Measures Assessment''); Appendix VI–B (''Impracticability Demonstration for Request for ''Serious'' Classification for 2012 Annual $PM_{2.5}$ Standard''; Appendix VI–C (''Reasonable Further Progress (RFP) and Milestone Years''), pages VI–C–5 through VI–C–14, and Attachment VI–C–1 (''California Existing Mobile Source Control Program''); Appendix VI–D (''General Conformity and Transportation Conformity Budget''), pages VI–D–2 through VI–D–4, excluding tables VI–D–1 and VI–D–2; and Appendix VI–F (''PM Precursor Requirements'').

* * * * *

■ 3. Section 52.248 is amended by adding paragraph (k) to read as follows:

§ 52.248 Identification of plan—conditional approval.

* * * * *

(k) The EPA is conditionally approving the California State Implementation Plan (SIP) for the South Coast with respect to the contingency measure requirement in CAA section 172(c)(9) for both the Serious area plan for the 2006 $PM_{2.5}$ NAAQS and the Moderate area plan for the 2012 $PM_{2.5}$ NAAQS. The conditional approval is based on a commitment from the South Coast Air Quality Management District (District) in a letter dated February 12, 2020, to adopt specific rule revisions, and a commitment from the California Air Resources Board (CARB) dated March 3, 2020, to submit the amended District rule to the EPA by the earlier of one year after the date of the EPA's conditional approval of the contingency measures for the 2012 annual $PM_{2.5}$ standard, or 60 days after the date the EPA determines that the South Coast area has failed to attain the 2006 24-hour $PM_{2.5}$ standards but no later than one year after the date of the EPA's conditional approval of the contingency measures for these standards. The EPA determined on September 16, 2020, that the South Coast area had failed to attain the 2006 24-hour $PM_{2.5}$ standards. Therefore, CARB must submit the amended District rule to the EPA by November 16, 2020. If the District or CARB fail to meet their commitments, the conditional approval is treated as a disapproval.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 4. The authority citation for part 81 continues to read as follows:

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

Subpart C—Section 107 Attainment Status Designations

■ 5. In § 81.305, amend the table ''California—2012 Annual $PM_{2.5}$ NAAQS [Primary],'' by revising the entries under ''Los Angeles-South Coast Air Basin, CA'' to read as follows:

§ 81.305 California.

* * * * *

CALIFORNIA—2012 ANNUAL $PM_{2.5}$ NAAQS

[Primary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Los Angeles-South Coast Air Basin, CA:				
Los Angeles County (part)		Nonattainment	December 9, 2020	Serious.

CALIFORNIA—2012 ANNUAL $PM_{2.5}$ NAAQS—Continued

[Primary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
That portion of Los Angeles County which lies south and west of a line described as follows: Beginning at the Los Angeles-San Bernardino County boundary and running west along the Township line common to Township 3 North and Township 2 North, San Bernardino Base and Meridian; then north along the range line common to Range 8 West and Range 9 West; then west along the Township line common to Township 4 North and Township 3 North; then north along the range line common to Range 12 West and Range 13 West to the southeast corner of Section 12, Township 5 North and Range 13 West; then west along the south boundaries of Sections 12, 11, 10, 9, 8, and 7, Township 5 North and Range 13 West to the boundary of the Angeles National Forest which is collinear with the range line common to Range 13 West and Range 14 West; then north and west along the Angeles National Forest boundary to the point of intersection with the Township line common to Township 7 North and Township 6 North (point is at the northwest corner of Section 4 in Township 6 North and Range 14 West); then west along the Township line common to Township 7 North and Township 6 North; then north along the range line common to Range 15 West and Range 16 West to the southeast corner of Section 13, Township 7 North and Range 16 West; then along the south boundaries of Sections 13, 14, 15, 16, 17, and 18, Township 7 North and Range 16 West; then north along the range line common to Range 16 West and Range 17 West to the north boundary of the Angeles National Forest (collinear with the Township line common to Township 8 North and Township 7 North); then west and north along the Angeles National Forest boundary to the point of intersection with the south boundary of the Rancho La Liebre Land Grant; then west and north along this land grant boundary to the Los Angeles-Kern County boundary.				
Orange County		Nonattainment	December 9, 2020	Serious.
Riverside County (part)		Nonattainment	December 9, 2020	Serious.
That portion of Riverside County which lies to the west of a line described as follows: Beginning at the Riverside-San Diego County boundary and running north along the range line common to Range 4 East and Range 3 East, San Bernardino Base and Meridian; then east along the Township line common to Township 8 South and Township 7 South; then north along the range line common to Range 5 East and Range 4 East; then west along the Township line common to Township 6 South and Township 7 South to the southwest corner of Section 34, Township 6 South, Range 4 East; then north along the west boundaries of Sections 34, 27, 22, 15, 10, and 3, Township 6 South, Range 4 East; then west along the Township line common to Township 5 South and Township 6 South; then north along the range line common to Range 4 East and Range 3 East; then west along the south boundaries of Sections 13, 14, 15, 16, 17, and 18, Township 5 South, Range 3 East; then north along the range line common to Range 2 East and Range 3 East; to the Riverside-San Bernardino County line.				
San Bernardino County (part)		Nonattainment	December 9, 2020	Serious.
That portion of San Bernardino County which lies south and west of a line described as follows: Beginning at the San Bernardino-Riverside County boundary and running north along the range line common to Range 3 East and Range 2 East, San Bernardino Base and Meridian; then west along the Township line common to Township 3 North and Township 2 North to the San Bernardino-Los Angeles County boundary.				
* * *	*	*	*	*

[1] Includes areas of Indian country located in each county or area, except as otherwise specified.
[2] This date is April 15, 2015, unless otherwise noted.

* * * * *

[FR Doc. 2020–23033 Filed 11–6–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02; RTID 0648–XA627]

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; fishery reopening.

SUMMARY: NMFS reopens the General category fishery for two days within the October through November 2020 General category subquota period. This action is intended to provide a reasonable opportunity to harvest the full annual U.S. bluefin tuna (BFT) quota without exceeding it, while maintaining an equitable distribution of fishing opportunities across time periods. This action applies to Atlantic tunas General category (commercial) permitted vessels and Atlantic Highly

Migratory Species (HMS) Charter/Headboat category permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

DATES: Effective 12:30 a.m., local time, November 7, 2020, through 11:30 p.m., local time, November 8, 2020.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin or Nicholas Velseboer, 978–281–9260, or Larry Redd, 301–427–8503.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments. NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

The current baseline General and Reserve category quotas are 555.7 mt and 29.5 mt, respectively. See § 635.27(a). Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a ''subquota'' or portion of the annual General category quota. The baseline subquotas for each time period are as follows: 29.5 mt for January; 277.9 mt for June through August; 147.3 mt for September; 72.2 mt for October through November; and 28.9 mt for December. Any unused General category quota rolls forward from one time period to the next, and is available for use in subsequent time periods. To date, NMFS has taken several actions that resulted in adjustments to the General and Reserve category quotas (85 FR 17, January 2, 2020; 85 FR 6828, February 6, 2020; 85 FR 43148, July 16, 2020; 85 FR 59445, September 22, 2020; 85 FR 61872, October 1, 2020; 85 FR 64411, October 13, 2020; and 85 FR 68798, October 30, 2020). In the most recent action (85 FR 68798), NMFS reopened the General category fishery for two days, October 28 and 29, 2020.

General Category Reopening

As of November 4, 2020, preliminary landings data indicate that the General category landed 103.5 mt before closing. This represents 81 percent of the adjusted October through November subquota of 127.7 mt. Under regulations at § 635.28(a)(2), NMFS may reopen the fishery if NMFS determines that reasonable fishing opportunities are available. Based on average October landings rates, NMFS has determined that reopening the General category fishery for two days is appropriate given the amount of unused October through November subquota (*i.e.,* 24.2 mt); depending on weather conditions and fish availability, a longer reopening could risk exceeding the unused quota available for the October through November subquota period. NMFS will need to account for 2020 landings and dead discards within the adjusted U.S. quota, consistent with ICCAT recommendations, and anticipates having sufficient quota to do that. NMFS anticipates that General category participants in all areas and time periods will have opportunities to harvest the General category quota in 2020, through active inseason management such as the timing of quota transfers, as practicable. Thus, this action would allow fishermen to take advantage of the availability of fish on the fishing grounds to the extent consistent with the available amount of quota and other management objectives, while avoiding quota exceedance.

Therefore, the General category fishery will reopen at 12:30 a.m., November 7, 2020, and close at 11:30 p.m., November 8, 2020. The General category daily retention limit during this reopening remains the same as prior to closing: one large medium or giant (*i.e.,* measuring 73 inches (185 cm) curved fork length or greater) bluefin tuna per vessel per day/trip. This action applies to Atlantic tunas General category (commercial) permitted vessels and HMS Charter/Headboat category permitted vessels with a commercial sale endorsement when fishing commercially for BFT. Retaining, possessing, or landing large medium or giant BFT by persons aboard vessels permitted in the General and HMS Charter/Headboat categories must cease at 11:30 p.m. local time on November 8, 2020.

The General category will automatically reopen December 1, 2020, for the December 2020 subquota time period (consistent with regulations at § 635.27(a)(1)) at the default one-fish level. In January 2020, NMFS adjusted the General category base subquota for the December 2020 period to 9.4 mt (85 FR 17, January 2, 2020). Based on quota availability in the Reserve, NMFS may consider transferring additional quota to the December subquota period, as appropriate.

Fishermen may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *https://www.fisheries.noaa.gov/resource/outreach-and-education/careful-catch-and-release-brochure/.*

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov,* using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments are necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is authorized by 50 CFR 635.28(a)(2), which was issued pursuant to section 304(c), and is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS finds that pursuant to 5 U.S.C.

553(b)(B), there is good cause to waive prior notice of, and an opportunity for public comment on, this action for the following reasons: The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Affording prior notice and opportunity for public comment to reopen the fishery is impracticable and contrary to the public interest. The General category recently closed, but based on available BFT quotas, fishery performance in recent weeks, and the availability of BFT on the fishing grounds, responsive reopening of the fishery is warranted to allow fishermen to take advantage of availability of fish and of quota. NMFS could not have proposed this action earlier, as it needed to consider and respond to updated data and information about fishery conditions and this year's landings. If NMFS was to offer a public comment period now, after having appropriately considered that data, it would preclude fishermen from harvesting BFT that are legally available. This action does not raise conservation and management concerns. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

Authority: 16 U.S.C. 971 et seq. and 1801 et seq.

Dated: November 4, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–24848 Filed 11–4–20; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[RTID 0648–XY104]

Fisheries of the Exclusive Economic Zone Off Alaska; St. Matthew Blue King Crab Rebuilding Plan in the Bering Sea and Aleutian Islands

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

ACTION: Notice of agency decision.

SUMMARY: The National Marine Fisheries Service (NMFS) announces the approval of Amendment 50 to the Fishery Management Plan (FMP) for Bering Sea/Aleutian Islands (BSAI) King and Tanner Crabs (Crab FMP) (Amendment 50). Amendment 50 adds a new rebuilding plan for St. Matthew blue king crab (SMBKC) to the Crab FMP. The objective of this amendment is to rebuild the SMBKC stock. In order to comply with provisions of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), this action is necessary to implement a rebuilding plan prior to the start of the 2020/2021 fishing season. Amendment 50 is intended to promote the goals and objectives of the Magnuson-Stevens Act, the Crab FMP, and other applicable laws.

DATES: The amendment was approved on October 13, 2020.

ADDRESSES: Electronic copies of Amendment 50 and the Environmental Assessment (referred to as the ''Analysis'') prepared for this action may be obtained from *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Megan Mackey, 907–586–7228.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Act requires that each regional fishery management council submit any FMP amendment it prepares to NMFS for review and approval, disapproval, or partial approval by the Secretary of Commerce (Secretary). The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP amendment, immediately publish a notice in the **Federal Register** announcing that the amendment is available for public review and comment.

The Notice of Availability (NOA) for Amendment 50 was published in the **Federal Register** on July 15, 2020 (85 FR 42817) with a 60-day comment period that ended on September 14, 2020. NMFS received two comments during the public comment on the NOA. NMFS is not disapproving any part of Amendment 50 in response to these comments. NMFS summarized and responded to these comments under Comments and Responses, below.

NMFS determined that Amendment 50 is consistent with the Magnuson-Stevens Act and other applicable laws, and the Secretary of Commerce approved Amendment 50 on October 13, 2020. The July 15, 2020 NOA contains additional information on this action. No changes to Federal regulations are necessary to implement the Amendment.

NMFS manages the crab fisheries in the exclusive economic zone under the Crab FMP. The North Pacific Fishery Management Council (Council) prepared the Crab FMP under the authority of the Magnuson-Stevens Act, 16 U.S.C. 1801 *et seq.* Regulations governing U.S. fisheries and implementing the FMP appear at 50 CFR parts 600 and 680.

Through the Crab FMP, the State of Alaska (the State) is delegated management authority over certain aspects of the SMBKC fishery consistent with the Magnuson-Stevens Act and the FMP. Specific to this Crab FMP amendment, the State has established a harvest strategy to set total allowable catch (TAC) levels and guideline harvest levels (GHLs), and season or area closures when the TAC or GHL is reached. The State's SMBKC harvest strategy (5 AAC 34.917) is more conservative than the Crab FMP's control rule parameters. Under the State's harvest strategy, directed fishing is prohibited at or below a larger biomass level than the Crab FMP's overfishing level (F_{OFL}) control rule. During rebuilding, the State's harvest strategy will apply.

NMFS declared the SMBKC stock overfished on October 22, 2018, because the estimated spawning biomass was below the minimum stock size threshold specified in the Crab FMP. In order to comply with provisions of the Magnuson-Stevens Act, a rebuilding plan must be implemented prior to the start of the 2020/2021 fishing season.

In June 2020, the Council chose a rebuilding plan for SMBKC that allows directed harvest during rebuilding only if estimates of stock biomass are sufficient to open the fishery under the State's crab harvest strategy. The rebuilding plan is consistent with the Magnuson-Stevens Act (16 U.S.C. 1854(e)); with the National Standards (see Analysis Section 4.1); and with National Standard Guidelines (50 CFR 600.310) on time for rebuilding, specifically rebuilding within a time (T_{target}) that is as short as possible, taking into account the status and biology of any overfished stocks of fish, the needs of fishing communities, recommendations by international organizations in which the United States participates, and the interaction of the overfished stock of fish with the marine ecosystem. This rebuilding plan will allow directed fishing pursuant to the State's harvest strategy because such fishing, though limited, may provide important economic opportunities for harvesters, processors, and Alaska communities. Maintaining these economic opportunities for a limited directed commercial fishery under the State harvest strategy is important for

harvesters, processors, and communities, particularly because the majority of commercial crab stocks are currently in a state of decline and future openings are likely to be limited or closed. Fishermen and communities must be able to diversify their portfolios and be flexible enough to take advantage of any available fishing opportunities each season to remain viable.

Under the Magnuson-Stevens Act, the time period specified for rebuilding a fishery generally should not exceed 10 years unless the biology of the stock or environmental conditions dictate otherwise, as is the case for SMBKC. Because ecological conditions represent the primary constraint on rebuilding the SMBKC fishery, the projected time for rebuilding, taking into account the biology of the species and current environmental conditions, is 25.5 years.

The directed fishery has been closed since 2016 under the State harvest strategy, and has only been open 6 out of the past 20 years. In addition to the State's conservative SMBKC harvest policy, multiple measures for habitat protection and bycatch reduction are in place for the stock. The St. Matthew Island Habitat Conservation Area (SMIHCA) was created in 2008 and expanded through Amendment 94 to the FMP for Groundfish of the BSAI Management Area to protect blue king crab habitat. Vessels fishing with non-pelagic trawl gear are prohibited from fishing in the SMIHCA. Other fishery closure areas include a 20 nautical mile (nmi) closure around the southern tip of Hall Island to trawling, hook-and-line, and pot fisheries for pollock, Pacific cod, and Atka mackerel to protect Steller sea lions, which also serves to limit fishing effort in areas occupied by SMBKC. In addition, State jurisdictional waters (0 to 3 nmi from shore) surrounding St. Matthew, Hall, and Pinnacle Islands are closed to the taking of king and Tanner crab and to commercial groundfish fishing.

Fishing mortality is not considered to be the primary constraining factor for rebuilding SMBKC. The groundfish fisheries incur low levels of bycatch of SMBKC, but in analytical projections average bycatch rates had no constraining effect on rebuilding (see Analysis Section 2.3). Instead, rebuilding will depend on successful recruitment of crab under ecosystem conditions that have recently been very unfavorable. Warm bottom temperatures, low pre-recruit biomass, and northward movement of predator species, primarily Pacific cod, have constrained stock growth (see Analysis Section 3.3.6). For this reason, the rebuilding plan aims to maintain existing low levels of fishing mortality with the anticipation that future ecosystem conditions will support SMBKC stock growth.

Amendment 50 adds Section 6.2.5 to the Crab FMP to include the approved rebuilding plan for SMBKC. Under the approved rebuilding plan, ecosystem indicators developed for the stock will be monitored for the foreseeable future. The NMFS eastern Bering Sea bottom-trawl survey provides data for the annual assessment of the status of crab stocks in the BSAI, including SMBKC, and this survey and assessment will continue throughout rebuilding. The Council's BSAI Crab Plan Team will report stock status and progress towards the rebuilt level in the Stock Assessment and Fishery Evaluation (SAFE) Report for the king and Tanner crab fisheries of the BSAI. Additionally, the State and NMFS monitor directed fishery catch and bycatch of blue king crabs in other fisheries. When the fishery is open, the State requires full observer coverage (100 percent) for both catcher vessels and catcher/processors participating in the crab fishery. Observers monitor harvest at sea and landings by catcher vessels to shoreside processors. The State reports the total harvest from the commercial crab fishery and that report will be included annually in the SAFE. The contribution of the rebuilding plan to stock recovery is additive to measures already in place that limit the effects of fishing activity on SMBKC.

Comments and Responses

During the public comment period for the NOA for Amendment 50, NMFS received two unique comments from two members of the public. NMFS is not disapproving any part of Amendment 50 in response to these comments. NMFS's responses to these comments are presented below.

Comment 1: One commenter expressed general support for this action.

Response: NMFS acknowledges this comment.

Comment 2: One commenter stated that crab fisheries in Alaska should be shut down.

Response: The Magnuson-Stevens Act and the Crab FMP require, among other things, that the Council and NMFS manage fisheries to prevent overfishing while achieving, on a continuing basis, the optimum yield from each fishery and base management decisions on the best scientific information available. The commenter provided no information to support shutting down crab fisheries in Alaska. Currently, crab fisheries in Alaska are being responsibly managed with conservative harvest strategies and provide important economic benefits to Alaskan communities.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 20, 2020.

Samuel D. Rauch III,

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

[FR Doc. 2020–23546 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 85, No. 217

Monday, November 9, 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 AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1280

RIN 0581–AC06

Lamb Promotion, Research, and Information Order; Correction

AGENCY: Agricultural Marketing Service, Department of Agriculture.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects the **SUPPLEMENTARY INFORMATION** to a proposed rule published in the **Federal Register** on October 5, 2020, regarding amendments to the Lamb Promotion, Research, and Information Order. This correction clarifies the assessment remittance process described in Examples 1 and 2 and removes the first paragraph in Example 5.

DATES: Comments must be received by December 4, 2020.

FOR FURTHER INFORMATION CONTACT: Jason Julian, Agricultural Marketing Specialist, Research and Promotion Division, Livestock and Poultry Program, AMS, USDA; telephone: (202) 731–2149; fax: (202) 720–1125; or email: *jason.julian@usda.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the proposed rule published at 85 FR 62617, beginning on page 62617 of the issue published on October 5, 2020, make the following corrections in the **SUPPLEMENTARY INFORMATION** section.

1. On page 62618, in the third column, second paragraph, replace the final sentence with the following:

''This procedure would change under the proposed rule.''

2. On page 62619, in the first column, replace the first paragraph with the following:

''Under the proposed rule, existing procedures in *Example 1* and *Example 2* would be replaced as shown in the following three scenarios.''

3. On page 62620, in the first column, remove the first paragraph.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–24754 Filed 11–6–20; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2020–0179]

RIN 3150–AK51

List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM UMAX Canister Storage System, Certificate of Compliance No. 1040, Amendment No. 4

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations by revising the Holtec International HI–STORM UMAX Canister Storage System listing within the ''List of approved spent fuel storage casks'' to include Amendment No. 4 to Certificate of Compliance No. 1040. Amendment No. 4 revises the certificate of compliance to update the technical specifications for radiation protection regarding the dose rate limit for the vertical ventilated module lid, update the technical specifications for the vent blockage limiting condition for operation, and add a Type 1 version of multi-purpose canister MPC–37.

DATES: Submit comments by December 9, 2020. Comments received after this date will be considered, if practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods.

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0179. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments,'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christian J. Jacobs, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6825; email: *Christian.Jacobs@nrc.gov* or Gerry L. Stirewalt, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–3698; email: *Gery.Stirewalt@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Obtaining Information and Submitting Comments
II. Rulemaking Procedure
III. Background
IV. Plain Writing
V. Availability of Documents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0179 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0179.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, instructions about obtaining

materials referenced in this document are provided in the ''Availability of Documents'' section.

• *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2020–0179 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on January 25, 2021. However, if the NRC receives any significant adverse comment by December 9, 2020, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For a more detailed discussion of the proposed rule changes and associated analyses, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule which added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled, ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on March 6, 2015 (80 FR 12073), as corrected (80 FR 15679; March 25, 2015), that approved the Holtec International HI–STORM UMAX Canister Storage System and added it to the list of NRC-approved cask designs in § 72.214, ''List of approved spent fuel storage casks,'' as Certificate of Compliance No. 1040.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Document	ADAMS package accession No.
Letter from Holtec International to NRC submitting the Amendment No. 4 Request for HI–STORM UMAX Canister Storage System Certificate of Compliance No. 1040, September 28, 2018.	ML18285A820.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, May 21, 2019.	ML19144A140.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, November 1, 2019.	ML19311C514.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, December 20, 2019.	ML20002A425.

Document	ADAMS package accession No.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, March 30, 2020.	ML20104C014.
Holtec International HI–STORM UMAX Amendment No. 4 Responses to Request for Additional Information, April 13, 2020.	ML20111A237.
User Need Memorandum to J. Cai from J. McKirgan with Proposed Certificate of Compliance No. 1040, Amendment No. 4; Associated Proposed Technical Specifications; and the Preliminary Safety Evaluation Report, July 21, 2020.	ML20161A087.

The NRC may post materials related to this document, including public comments, on the Federal Rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2020–0179. The Federal Rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC–2020–0179); (2) click the ''Sign up for Email Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (*i.e.,* daily, weekly, or monthly).

Dated October 21, 2020.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2020–24321 Filed 11–6–20; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1253

RIN 2590–AA17

Prior Approval for Enterprise Products

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of proposed rulemaking: request for comments.

SUMMARY: The Federal Housing Finance Agency (FHFA or Agency) is seeking comment on a proposed rule to implement section 1321 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended by section 1123 of the Housing and Economic Recovery Act of 2008. This proposed rule, if adopted, would replace a 2009 interim final rule that established a process for the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Enterprises) to obtain prior approval from the FHFA Director for a new product and provide prior notice to the Director of a new activity.

DATES: Written comments must be received on or before January 8, 2021.

ADDRESSES: You may submit your comments on the proposed rule, identified by regulatory information number (RIN) 2590–AA17, by any one of the following methods:

- *Agency website: www.fhfa.gov/open-for-comment-or-input.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by email to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by FHFA. Include the following information in the subject line of your submission: Comments/RIN 2590–AA17.
- *Hand Delivered/Courier:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590–AA17, Federal Housing Finance Agency, Eighth Floor, 400 Seventh Street SW, Washington, DC 20219. Deliver the package at the Seventh Street SW, entrance Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.
- *U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service:* The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2590–AA17, Federal Housing Finance Agency, Eighth Floor, 400 Seventh Street SW, Washington, DC 20219. Please note that all mail sent to FHFA via U.S. Mail is routed through a national irradiation facility, a process that may delay delivery by approximately two weeks. For any time-sensitive correspondence, please plan accordingly.

FOR FURTHER INFORMATION CONTACT: Susan Cooper (202) 649–3121, *susan.cooper@fhfa.gov,* Office of Housing and Regulatory Policy; or Miriam Smolen (202) 230–2987, *miriam.smolen@fhfa.gov,* Office of General Counsel, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. These are not toll-free numbers. The telephone number for the Telecommunications Device for the Deaf is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Comments and Access

FHFA invites comments on all aspects of the proposed rule and will take all comments into consideration before issuing a final rule. Copies of all comments will be posted without change, and will include any personal information you provide such as your name, address, email address, and telephone number, on the FHFA website at *http://www.fhfa.gov.* In addition, copies of all comments received will be available for examination by the public through the electronic rulemaking docket for this proposed rule also located on the FHFA website.

II. Background

A. Statutory Background

Through products offered to the marketplace and their activities in the housing finance system, Fannie Mae and Freddie Mac, together, own or guarantee nearly $5.6 [1] trillion of residential mortgages in the United States as of Q1 2020. Their products play a key role in housing finance and the U.S. economy. The Enterprises, while continuing to serve their public missions, are motivated to seek out new technological advances and pursue innovations, which can create new opportunities to provide the public, counterparties, and the market more access to and options for products. However, the Enterprises also take on risks, and create risks for themselves and the mortgage finance, financial system and the broader economy, through their activities and product offerings. The parameters of certain new activities and products may also raise questions of how successfully such new activities and products achieve the Enterprises' public missions against the risks created through such actions.

Recognizing the significant effects that Enterprise products and activities have on the market and market participants, the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended (12 U.S.C. 4501 *et seq.*) (the Safety and Soundness Act or Act) empowered the FHFA Director to review products prior to the products being offered to the market. Specifically, the Safety and Soundness Act requires ''each [E]nterprise to obtain the approval of the

[1] *See https://fred.stlouisfed.org/release/tables?rid=52&eid=1192326.*

Director for any product of the [E]nterprise before initially offering the product.'' *See* section 1321(a) of the Safety and Soundness Act (12 U.S.C. 4541(a)).

The Safety and Soundness Act makes a distinction between an activity and a product, and provides for the Enterprise to submit information to FHFA so that the Director may make certain determinations related to that distinction. The Safety and Soundness Act uses the term ''product'' when discussing products which are new for an Enterprise, and the language ''new and existing products or activities'' when discussing products and activities both new and already in existence. For ease of understanding, the proposed rule and this supplementary information use the term ''new product'' and ''new activity'' consistently to describe a product and activity which either does not exist at all, or exists in a different form, at the time of the effective date of the proposed rule when it becomes final.

Before commencing a new activity that an Enterprise does not consider to be a product, the Safety and Soundness Act requires an Enterprise to provide ''written notice'' to the Director for a determination of whether such an activity is a product subject to prior approval under section 1321. *See* section 1321(e)(2) of the Safety and Soundness Act (12 U.S.C. 4541(e)(2)). If the Director determines such a new activity to be a new product, the Enterprise shall ''obtain the approval of the Director for any product of the [E]nterprise before initially offering the product.'' *See* section 1321(a) of the Safety and Soundness Act (12 U.S.C. 4541(a)). In considering any request for approval of a new product, the Director shall make a determination whether the product is authorized pursuant to certain sections of the Enterprises' authorizing statutes,[2] whether it is in the public interest, and whether it is consistent with the safety and soundness of the Enterprise or the mortgage finance system. *See* section 1321(b) of the Safety and Soundness Act (12 U.S.C. 4541(b)). As part of the process for the Director's approval of a new product, the Safety and Soundness Act provides a timeline for receipt and review of public comment regarding the proposed product. *See* section 1321(c) of the Safety and Soundness Act (12 U.S.C. 4541(c)).

The Safety and Soundness Act excludes automated loan underwriting systems and mortgage terms and conditions, and certain upgrades and modifications to those activities, from the requirements of section 1321 of the Safety and Soundness Act (12 U.S.C. 4541). *See* section 1321(e) of the Safety and Soundness Act (12 U.S.C. 4541(e)). The Act also excludes ''any other activity that is substantially similar'' to the above activities, and to ''activities that have been approved by the Director in accordance with this section.'' *Id.* The Director's safety and soundness authority is not restricted by this provision of the Safety and Soundness Act, nor is his authority to determine that the Enterprise's activities are consistent with its statutory mission. *See* section 1321(f) of the Safety and Soundness Act (12 U.S.C. 4541(f)).

B. Interim Final Rule

FHFA adopted an Interim Final Rule for Prior Approval for Enterprise Products (Interim Final Rule) which became effective on July 2, 2009, and remains in effect. Interim Final Rule, 12 CFR 1253.[3] That rule established an interim approach to implementing the Act's provisions pertaining to the process for the Enterprises to obtain prior approval from the FHFA Director for a new product and provide prior notice to the Director of a new activity. This proposed rule, if adopted as final, would replace the Interim Final Rule. However, until this proposed rule becomes final and effective, the Prior Approval for Enterprise Products regulation established under the Interim Final Rule shall remain in force and effect.

The Interim Final Rule provides the requirements for an Enterprise to gain prior approval for an Enterprise product. The Interim Final Rule also provides that an Enterprise must submit a Notice of New Activity regarding a new activity or new product, and the Rule included a Notice of New Activity form in an appendix. *See* Interim Final Rule, Appendix to 12 CFR part 1253. The form includes instructions on providing the required information, and additional instructions are also provided in the Appendix, including criteria for identifying a new activity and new product.

FHFA received a small number of comments on the Interim Final Rule, including from the Enterprises. While FHFA has reviewed those comments, the lengthy passage of time and the change in circumstance for the Enterprises from 2009, support providing those parties and other members of the public an opportunity to provide new comments on this proposed rule.

C. Conservatorship

On September 6, 2008, the Director of FHFA appointed FHFA as conservator of the Enterprises in accordance with the Safety and Soundness Act to stabilize the Enterprises and to help assure performance of their public mission. In September 2019, the U.S. Treasury Department released its housing reform plan that recommended that FHFA begin the process to end each Enterprises' conservatorship in a manner consistent with the preconditions set forth in that plan.[4] In October 2019, FHFA issued a new Strategic Plan and Scorecard for the Enterprises that stated that ''[e]nding the conservatorships of Fannie Mae and Freddie Mac is a central and necessary element of this new roadmap.''

The Interim Final Rule has been in effect during the majority of the time of the conservatorships of the Enterprises. In light of FHFA's obligation to end the conservatorships, this proposed rule, if adopted as a final rule, would be in operation both during and after the Enterprises' transition from conservatorship. Therefore, FHFA believes it is important to propose the Prior Approval for Enterprise Products rule which will replace the Interim Final Rule to afford interested parties an opportunity to comment on the scope of the proposed rule and the process for submission and FHFA review of a new activity and new product.

III. Discussion of Proposed Rule

A. Overview of the Proposed Rule

The proposed rule would provide the criteria for what is a new activity and a new product, and the process for that activity's review and approval by the Director. Although the Act does not provide definitions for a product or an activity, or for how to identify what is ''new,'' the proposed rule provides distinguishing characteristics in order to implement the statutory mandate for the Director to approve a new product prior to an Enterprise offering that product. The standard for approving a new product includes determinations that the product complies with the

[2] Fannie Mae's authorizing statute is the Federal National Mortgage Association Charter Act (12 U.S.C. 1716 *et seq.*). Freddie Mac's authorizing statute is the Federal Home Loan Mortgage Corporation Act (12 U.S.C. 1451 *et seq.*).

[3] References to the Interim Final Rule, at 74 FR 31602 (July 2, 2009), will include the description ''Interim Final Rule, 12 CFR part 1253 or 12 CFR and the corresponding section.'' References to the proposed rule will refer to the section of the proposed rule in part 1253.

[4] Treasury, Housing Reform Plan at 26 (Sept. 2019), available at *https://home.treasury.gov/system/files/136/Treasury-Housing-Finance-Reform-Plan.pdf.*

Enterprises' authorizing statutes, that it is in the public interest, and that it is consistent with the safety and soundness of the Enterprise or the mortgage finance system. *See* section 1321(b) of the Safety and Soundness Act (12 U.S.C. 4541(b)). Because of the lack of definitions, and the breadth of the considerations relevant to approval, FHFA concludes that the determination of whether a new activity is a new product in specific instances is committed to Agency discretion by law.

The Act has separate provisions for a request for prior approval of a new product and for a notice of a new activity that the Enterprise does not believe to be a new product. However, FHFA does not believe that it is practical to require an Enterprise to identify a new product in advance—as distinct from a new activity that is not a new product—for purposes of determining which type of submission to make to the Agency. For that reason, the proposed rule provides for a unified notice process which requires an Enterprise to make a single form of submission—a Notice of New Activity. A single submission will also streamline the review conducted by FHFA.

Both the Act and the Interim Final Rule set the parameters of the activities that fall within the scope of the Act through a set of exclusions to the requirements of the Act. Not all new activities, even if ''new'' by virtue of date, are to be reviewed as a possible new product if they are excluded through either statutory, or additional regulatory, exclusions. Both the Interim Final Rule and proposed rule follow the Act's framework, but also provide criteria for how to identify a new activity. The Interim Final Rule provided a form for the Notice of New Activity and instructions regarding the content for the form and to aid the Enterprise in identifying a new activity and new product. The proposed rule incorporates the Interim Final Rule's substantive criteria for a new activity and new product into the regulation text in a reorganized and more streamlined format. In addition, in the proposed rule, FHFA seeks to streamline and simplify the content and submission of a Notice of New Activity by incorporating the required content into the regulation text rather than in a specific form as part of an appendix to the regulation.

In establishing the criteria by which to identify a new activity, the proposed rule would employ, as much as possible, objective characteristics that can be commonly understood. The proposed rule limits the use of terms such as ''substantial,'' ''significant,'' or ''*de minimis*'' because of the lack of a clear, common understanding of such subjective terms. Where those terms are used, additional guidance is provided in this supplementary information to align the meaning of the terms.

As provided in the Safety and Soundness Act, 12 U.S.C. 4541(f), the Director's exercise of his or her authority under the regulations in this part in no way restricts the Director's safety and soundness authority over all new and existing products or activities of an Enterprise, or the Director's authority to review all new and existing products or activities to determine that such products or activities are consistent with the statutory mission of an Enterprise.

B. New Activity and New Product

The proposed rule at § 1253.3 would describe the criteria for identifying a new activity and also describe the activities that are excluded from the requirements of the proposed rule.[5] New activities meeting these criteria merit review by FHFA because they may implicate considerations of compliance with the Enterprises' authorizing statutes, safety and soundness, and the public interest.

Section 1253.3(a)(1) of the proposed rule would provide a description of the nature of an ''activity'' to distinguish the universe of actions that are within the scope of the proposed rule from the total business operations of an Enterprise. An activity would be a business line, business practice, offering or service, including guarantee, financial instrument, consulting or marketing, that the Enterprise provides to the market either on a standalone basis or as part of a business line, business practice, offering, or service.

Section 1253.3(a)(2) of the proposed rule would provide the specific criteria that identify an activity as ''new.'' A threshold criterion for a new activity is timing—that an activity is not currently engaged by the Enterprise as of the effective date of this proposed rule when final, or is an enhancement, alteration, or modification to an existing activity that the Enterprise currently engages in as of the effective date of this proposed rule when final.

The proposed rule would set the trigger date for new activities to be the effective date of the final rule. This is different than the Interim Final Rule which used the trigger date of July 30, 2008. To the extent that the Enterprises have initiated new activities in the time period between July 30, 2008 and what will be the effective date of the final rule, the Interim Final rule has been in effect. Importantly also, during this time period, both Enterprises have, and continue to be, in conservatorship which provides special conservator review of Enterprise activities in addition to FHFA's standard supervisory and regulatory oversight. Given the passage of time and the evolution of the Enterprises' business activities since the date of the Interim Final Rule, FHFA determined that the appropriate trigger date for the proposed rule would be the effective date of a final rule so the proposed rule looks forward, rather than retroactively.

In addition to meeting the requirements of proposed § 1253.3(a)(1) and (2), a new activity must be an activity which is described by one or more of the criteria provided at proposed § 1253.3(a)(3). The first three of these criteria are that an activity: (1) Requires a new type of resource, a new type of data, a new policy or modification to an existing policy, a new process or infrastructure; (2) Expands the scope or increases the level of credit risk, market risk, or operational risk to the Enterprise; or (3) Involves a new category of borrowers, investors, counterparties, or collateral.

These elements use objective criteria to distinguish a new activity from an ongoing activity and to identify common attributes that may appear in business activities that are innovations or different from ongoing activity. For example, a new activity that uses a new type of data would include collecting a data item from an external party that had not been collected or used before by an Enterprise versus an activity that uses or collects the same type of data but uses it in a different format or captures an additional field for use in the same way. Similarly, an expansion of an existing activity that requires additional resources of the type already in use would not be captured by the resource criterion; however, a new type of resource that indicates a new activity could be a new organizational division, or newly contracted vendors for a different type of service. While expansion of an existing activity is not, per se, a new activity, that expansion may indicate a new activity if that enlargement expands the scope or increases the level of credit risk, market risk, or operational risk to the Enterprise.

[5] OFHEO capital regulation for the Enterprises, 12 CFR part 1750, subpart B, App. A (Risk-based capital) provides for a definition for new activity, which applies to the relevant section of that appendix, and is not controlling for purposes of 12 CFR part 1253. In any event, 12 CFR part 1750 in its entirety is proposed to be removed as part of the proposed rule for Enterprise Regulatory Capital Framework, 12 CFR part 1240, at 85 FR 39274 (June 30, 2020).

Section 1253.3(a)(3)(iv) of the proposed rule provides that a new activity can be identified if it would substantially impact the mortgage finance system, the Enterprise's safety and soundness, compliance with the Enterprise's authorizing statute, or the public interest. FHFA expects that the Enterprise will identify as a new activity an activity which would raise these systemic, statutory, or regulatory issues.

Section 1253.3(a)(3)(v) and (vi) of the proposed rule provides the final two categories for identifying a new activity: (1) A pilot; or (2) An activity resulting from a pilot that is described by one of the criteria discussed above. The Interim Final Rule also specifically identified pilots as being in scope of a new activity. *See* Interim Final Rule, Appendix to 12 CFR part 1253, Section (A)(1). The proposed rule would define a pilot to be an activity that has a defined term and scope for purposes of understanding the viability of a new offering. For purposes of inclusion in the proposed rule, a pilot includes activities called by various other names such as testing initiative, test and learn, or temporary authorization. Unless a pilot falls into one of the exclusions set forth at proposed § 1253.3(b), FHFA would expect a Notice of New Activity to be submitted even if the pilot did not trigger one of the other paragraphs of proposed § 1253.3(a), such as increasing the level of risk to the Enterprise or requiring new resources. Despite possible limited size or financial impact on the Enterprises and the markets, pilots sometimes have an outsized effect in other areas such as furthering technological change or concerning the Enterprise mission. An additional variable is that pilots often extend for lengthy periods of time and sometimes change form as a natural consequence of conducting exploratory types of business.

If an Enterprise decides that an activity should emerge from its pilot status to be a continuing activity, an Enterprise should evaluate whether that activity triggers one of the criteria discussed above and, if so, should again submit a Notice of New Activity. An activity emerging from a pilot is not an ''enhancement, alteration or modification'' to the existing pilot but a new activity that needs to be submitted in a new Notice of New Activity. As discussed below in Section III.G, regarding the content of a Notice of New Activity, the Enterprise should plan to include as part of the Notice, an analysis on the effectiveness of, and modifications to, the pilot as part of its rationale for a broader offering. This will assist FHFA in its review as to whether the activity emerging from the pilot requires a public notice and comment review.

FHFA recognizes that providing examples to help explain when FHFA would consider an activity to be a new activity is useful for commenters. The examples given are for illustrative purposes only and should not be construed as a position that FHFA may take on whether an activity is permissible under the Enterprise's authorizing statute, or would be a new activity or a new product under the proposed rule. All the examples presume that the activity meets the baseline criteria that are set out in proposed § 1253.3.

1. Example—Activity Which Is a Business Line Offering

Currently, the Enterprises do not acquire personal property loans for manufactured housing (chattel loans). Under the proposed rule, if an Enterprise planned to offer a chattel loan product offering, such an activity would fall within at least three categories under proposed § 1253.3. To support such an offering, an Enterprise would need to develop new policies or modify existing ones, as well as implement new processes or infrastructure, in order to acquire and securitize chattel loans. This activity would expand the scope or increase the level of credit risk, market risk, or operational risk to the Enterprise given the nature of the underlying collateral. Also, this is an activity that would involve a new category of collateral because it is not titled as real estate, and possibly a new category of borrowers, investors, or counterparties. A chattel loan product may also have a substantial impact on the public interest because of the affordable nature of manufactured housing and the potential for enhancing consumer protections through the origination and servicing requirements established by an Enterprise. In this example, the Enterprise must submit a Notice of New Activity prior to offering this product to the market.

2. Example—Activity Which Is a Pilot

While in conservatorship, the Enterprises have previously engaged in pilots within their multifamily business lines that facilitated financing for institutional operators of single-family rental (SFR) properties; they are not actively engaged in this type of pilot currently. Under the proposed rule, if an Enterprise wanted to re-engage in this type of pilot, the category for pilots would trigger the requirement to submit a Notice of New Activity to FHFA.

Should an Enterprise decide to offer a product that facilitated the financing for institutional operators of SFR properties, there are other categories under proposed § 1253.3 that would trigger the requirement to submit a Notice of New Activity to FHFA. For instance, such an offering for SFR properties would not only introduce a new type of collateral for an Enterprise's multifamily business line, but also would have an impact on the public interest because the product offering could place constraints on the single-family mortgage market by reducing the inventory of single-family homes available for purchase in a particular community.

3. Example—Activity Which Is a Loan Product Previously Offered But Not Offered as of the Effective Date of the Final Rule

In December 2008, Fannie Mae retired its reverse mortgage product Home Keeper, and in October 2010 it stopped acquiring the U.S. Department of Housing and Urban Development's (HUD) Home Equity Conversion Mortgage (HECM).[6] Under the proposed rule, if Fannie Mae wanted to resume acquisition of a reverse mortgage product after the effective date of the final rule, at least two of the categories under proposed § 1253.3 would trigger the requirement to submit a Notice of New Activity to FHFA. In order to resume acquisitions, Fannie Mae would have to re-establish the policies, processes, and infrastructure to support new acquisitions. The activity would also include an increased level of credit risk, market risk, or operational risk to the Enterprise. This example illustrates that even though an Enterprise previously offered a product and then stopped offering it prior to the effective date of the final rule, the Enterprise must submit a Notice of New Activity to FHFA prior to offering the product to the market.

1. *FHFA requests comments on the scope of the criteria for identifying a new activity, specifically on whether they are sufficient for capturing an activity that would require an Enterprise to submit Notice of a New Activity to FHFA.*

2. *FHFA requests comments on whether the criteria used to identify a new activity are unambiguous and transparent or, if not, how they can be improved.*

[6] Fannie Mae still has Home Keeper mortgages and HECMs in its retained portfolio and maintains servicing requirements for these mortgages in its Servicing Guide. Freddie Mac did not offer a reverse mortgage product.

C. Exclusions From New Activity and New Product

Section 1253.3(b) of the proposed rule would set forth those activities, as defined by the Act and the regulation, that are excluded from the requirements of the proposed rule. For purposes of consistency and practical application, the proposed rule provides that the exclusions apply when an activity is being evaluated for whether it is a new activity. Since only an activity that meets the criteria for a new activity is required to be evaluated as a new product, the exclusions apply to new products as well. For all but one of the exclusions, no notice or submission to FHFA is required prior to engaging in these activities because these activities are outside the scope of the prior approval requirements.

The Safety and Soundness Act and the Interim Final Rule expressly exclude activities involving the Enterprises respective automated underwriting systems in existence as of July 30, 2008 (Fannie Mae's Desktop Underwriter and Freddie Mac's Loan Product Advisor), including any upgrade to the technology, operating system, or software to operate the underwriting system. Since July 30, 2008, the Enterprises have made many upgrades to their automated underwriting systems and these upgrades fall within the exclusion.

However, technology systems which are not part of the automated underwriting systems would not fall into the exclusion. For example, the technology systems that evaluate the appraised value of a property, such as Fannie Mae's Collateral Underwriter (CU) or Freddie Mac's Home Value Explorer (HVE) or Loan Collateral Advisor, would not fall within this exclusion. These particular technologies predate the effective date of the proposed rule (when it is finalized) and so are outside the rule's scope. However, if changes are made to these systems which demonstrate one of the criteria of a new activity (such as a new type of data), those changes would need to be submitted in a Notice of New Activity.

The Safety and Soundness Act and proposed rule at proposed § 1253.3(b)(2) also exclude Enterprise activities that involve any modification to the Enterprise's mortgage product terms and conditions or mortgage underwriting criteria, provided that the modifications do not alter the underlying transaction to include services or financing for anything other than residential mortgages. For example, if an Enterprise modifies the maximum loan-to-value ratio for certain product offerings, such a modification would be excluded from the requirements of the proposed rule.

The Safety and Soundness Act and proposed rule at proposed § 1253.3(b)(3) excludes activities that are ''substantially similar'' to the automated underwriting systems and mortgage terms activities discussed above. As a guideline, the proposed rule would explain that if the activity is described by one or more of the criteria describing a new activity at proposed § 1253.3(a)(3)(i) through (iv)—such as requiring a new type of data or a new policy—the activity is not substantially similar and the Enterprise should submit a Notice of New Activity for review under the provisions of this section and may not proceed with the new activity except pursuant to the requirements in this section.

Section 1253.3(b)(5) of the proposed rule would include an additional regulatory exclusion, also included in the Interim Final Rule, which is for ''[a]ny Enterprise business practice, transactions, or conduct performed solely to facilitate the administration of an Enterprise's internal affairs to conduct its business.'' This exclusion clarifies that administration of the Enterprise's internal affairs are not subject to the proposed rule. This exclusion, however, is limited to an Enterprise's internal affairs—such as human resources—and does not exclude activity which ultimately impacts an offering to the public. No notice or submission to FHFA is required prior to engaging in the above described exclusions.

The final exclusion at proposed § 1253.3(b)(4) is an exclusion for an activity substantially similar to an approved new product. Unlike the exclusions described above, notice to FHFA is required prior to engaging in an activity falling within the scope of this exclusion. A detailed discussion of this exclusion is provided in Section F below.

3. *FHFA requests comments on how the exclusion for the automated underwriting systems as set forth in the Safety and Soundness Act should be applied to related but independent systems and to future technology systems.*

4. *FHFA requests comments on whether the exclusions should be narrowed or expanded, consistent with the Safety and Soundness Act.*

D. Public Notice and Comment for a New Product Review

Whether a new activity is a new product depends on whether the Director determines that the new activity merits public notice and comment on matters of: Compliance with the authorizing statutes of Fannie Mae or Freddie Mac; safety and soundness of the Enterprise or the mortgage finance system; or serving the public interest. Proposed § 1253.4 would set forth the factors that the Director may consider when determining whether a new product is in the public interest. These factors remain unchanged from the Interim Final Rule, apart from the deletion of the factor which stated ''other alternatives for providing the new product'' (Interim Final Rule, 12 CFR 1253.4(b)(3)(iv)), because that information is already requested in other factors. The Director retains the discretion to include other factors determined to be appropriate to consider during the approval process. The factors are ones the public should take into consideration in compiling their comments about a potential new product to inform the Director.

5. *FHFA requests comment on any other factors FHFA should include in the consideration of whether a new product is in the public interest.*

E. Process for Submission and Review of Notice of New Activity

Section 1253.5 of the proposed rule would establish the requirements for submission of a Notice of New Activity, and the review and determination process by FHFA, incorporating the timelines established by the Safety and Soundness Act. Before commencing any new activity, an Enterprise must submit to FHFA a written Notice of New Activity, the content of which is described in proposed § 1253.9. An Enterprise includes any of its affiliates, *see* 12 CFR 1201.1, and, if the new activity is to be offered by an affiliate, either the Enterprises or their affiliates may submit the Notice of New Activity. The Notice of New Activity provides a mechanism for the Director to determine whether the new activity is a new product in accordance with 12 U.S.C. 4541 and 12 CFR part 1253.

A Notice of New Activity will not be considered complete and received for processing until the information required by proposed § 1253.9 has been submitted, including any follow-up information required by FHFA. Section 1253.5(b) of the proposed rule would provide that nothing in the rule limits or restricts FHFA from reviewing the Notice of New Activity under any other applicable regulation or statute, as part of FHFA's authorities to review for safety and soundness and for consistency with an Enterprise's statutory mission. FHFA may conduct

such a review as part of its determination that the submission is complete. For example, if a proposed new activity necessitated a review for compliance with the Uniform Mortgage-Backed Security regulation (12 CFR part 1248), being in receipt of the information to be able to conduct that review may be part of FHFA's determination that the submission is complete and has been received.

The proposed rule would provide that an Enterprise may not commence a new activity unless the Director makes a written determination that the new activity is not a new product within 15 days, or the 15 days pass and no determination is made. If the Director determines that the new activity is a new product, the Enterprise must await approval of the new product under proposed § 1253.6. If there is a determination that the new activity is not a new product, or the 15 days pass with no determination, the Enterprise may begin the new activity, however undertaking the new activity may be subject to terms, conditions, or limitations as the Director may establish.

F. New Product Approval

Section 1253.6 of the proposed rule provides for public notice and comment of a new product. If the Director determines that the new activity is a new product, the proposed rule would provide that FHFA publish a public notice soliciting comments on the new product for a 30-day period. FHFA would include in that public notice enough information from the Notice of New Activity to sufficiently describe the new product, so that the public can provide comment. The public notice will state the closing date of the public comment period and will provide instructions for submission of public comment. As is the practice with other requests for information and proposed rules, comments submitted by the public on a new product will be made public and are posted on an FHFA website. The proposed rule does not include the confidentiality provision from the Interim Final Rule (§ 1253.5) as the proposed rule follows common practice that public comments will be made public. The Interim Final Rule confidentiality provision had also applied to the Enterprises' submission of information; in the proposed rule, FHFA will determine what information is necessary for the public notice.

In making the determination on approval of the new product, the Director will consider all public comments received by the closing date of the comment period. The proposed regulation incorporates the Safety and Soundness Act's approval requirements and would provide that the Director may approve the new product if the Director determines that the new product: In the case of Fannie Mae, is authorized under 12 U.S.C. 1717(b)(2), (3), (4), or (5) or 12 U.S.C. 1719; or in the case of Freddie Mac, is authorized under 12 U.S.C. 1454(a)(1), (4), or (5); is in the public interest; and is consistent with the safety and soundness of the Enterprise or the mortgage finance system.

In accordance with the statutory timelines, the Director will make a determination on the new product no later than 30 days after the close of the public comment period. If no determination is made within that time frame, the Enterprise may offer the new product. As with a new activity, a new product may be subject to any terms, conditions, or limitations as the Director may establish. Also, as with a new activity, the Director's authority to review for safety and soundness or consistency with the Enterprise's statutory mission is not compromised by any time limit provided for in the Act and reflected in the proposed rule.

Section 1253.7 of the proposed rule incorporates the statutory provision concerning making a new product available without first seeking public comment. Section 1321(c) of the Safety and Soundness Act (12 U.S.C. 4541(c)) authorizes the Director to grant ''temporary approval'' of the new product if exigent circumstances exist that make the delay associated with seeking public comment contrary to public interest. *See* section 1321 paragraphs (c)(2) through (c)(4) of the Safety and Soundness Act (12 U.S.C. 4541(c)(2) through (c)(4)). Accordingly, once FHFA determines that a new activity is a new product, FHFA will publish notice, along with a description of the new product for a 30-day public comment period, unless the Director determines that delay associated with first seeking public comment is contrary to public interest. The proposed rule would provide that where the Director determines that exigent circumstances exist such that delay associated with seeking public comment is contrary to public interest, the Director may consider and temporarily approve the new product without providing an advance public comment period. The Enterprise may request a Temporary Approval, or FHFA may act on its own initiative. The Director may impose terms, conditions or limitations on the Temporary Approval, and will also provide for a public comment period after granting the Temporary Approval.

Section 1253.8 of the proposed rule would describe the scope of the ''substantially similar'' exclusion for approved new products that appears at proposed § 1253.3(b)(4). The Safety and Soundness Act provides an exclusion to its requirements for prior approval for ''other activities that have been approved by the Director in accordance with this section.'' *See* section 1321(e) of the Safety and Soundness Act (12 U.S.C. 4541(e)). Once the Director determines that a new activity submitted in a Notice of New Activity is a new product, the new product will be published in a notice soliciting public comments. The Safety and Soundness Act provides that an Enterprise may offer a product if the Director approves the product, or if the Director does not make a determination within 30 days after the end of the public comment period; this requirement is incorporated in the proposed rule at proposed § 1253.6(c) and (g). *See* section 1321(e) of the Safety and Soundness Act (12 U.S.C. 4541(e)). The proposed rule would set out how the substantially similar exclusion for approved new products operates for the two types of circumstances leading to the offering of a new product for both the Enterprise that originally submitted the Notice of New Activity and the other Enterprise.

Section 1253.8 of the proposed rule would provide that either Enterprise may offer a new product that the Director has approved for the other Enterprise, or a new product that may be offered because no determination was made within the time period. This section covers both an activity which is the same as the original new product, and an activity that is substantially similar to the original new product. In either case, public notice and comment is not required because public notice and comment has already occurred in connection with the original offering. An Enterprise must notify FHFA of its intent to offer the new product at least 15 days prior, so that FHFA may exercise its regulatory and supervisory responsibilities. The notice is an abbreviated notice (not a Notice of New Activity) and the proposed content is the activity name and description, and, if the activity is substantially similar, why the Enterprise believes that to be the case. Notice is required here, unlike for the other exclusions which do not require notice, to ensure the product is the same or substantially similar to the original product and to ensure compliance with any conditions the Director may have placed on offering the original new product.

The Director may determine that the activity is not substantially similar to the original new product. If that is the case, the Enterprise would be required to submit a Notice of New Activity and proceed through the full approval process. As a guidepost, the proposed rule explains that if an activity is described by one or more of the criteria for determining whether an activity is a new activity—such as involving a new policy or a new category of borrower—the Director may determine that the activity is not substantially similar. This ''substantially similar'' exclusion does not cover a new activity which is not determined by the Director to be a new product as that new activity does not go through the public comment and approval process. This is consistent with the provision in the Interim Final Rule which limited this exclusion to the definition of ''New product.'' *See* Interim Final Rule § 1253.2.

Figure 1: Decision Tree below describes the decision paths for an original new product, for the same new product offered by the other Enterprise, and for a substantially similar new product for either Enterprise.

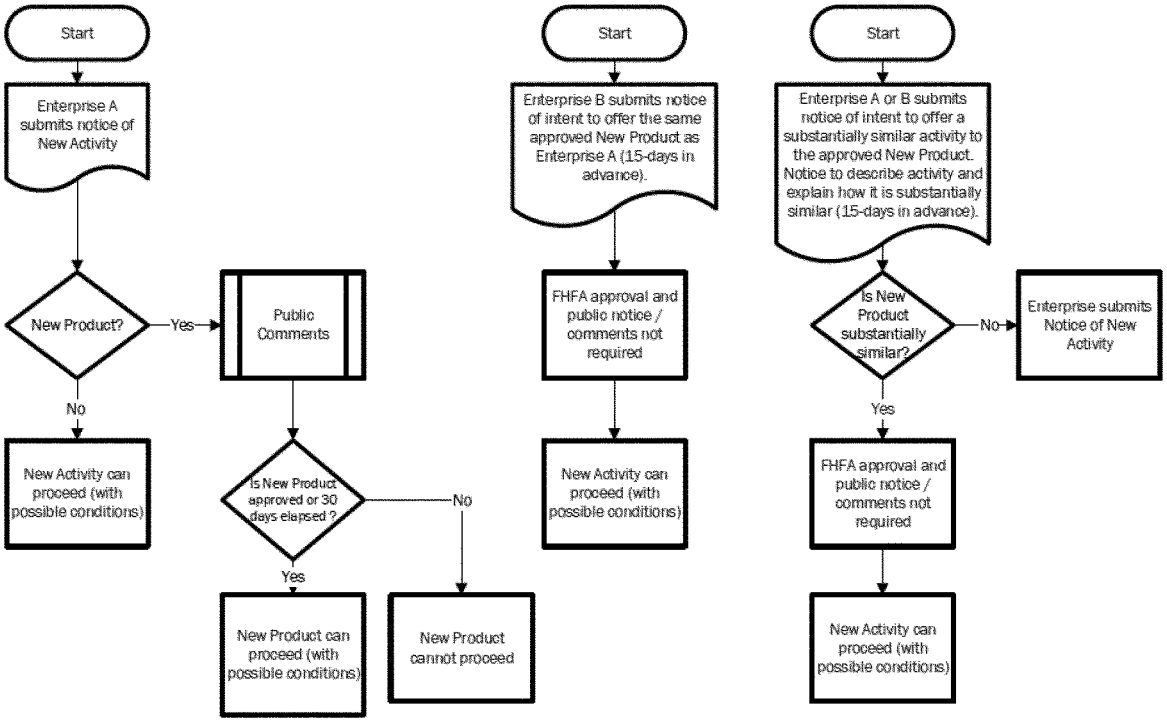

Figure 1: Decision Tree

6. *FHFA requests comment on whether the scope of the exclusion described in proposed § 1253.8 is too broad or too narrow, given the requirements of the Safety and Soundness Act.*

G. Notice of New Activity

The scope of the information required in a Notice of New Activity, as set out in proposed § 1253.9, serves to allow FHFA to: (1) Assess the impact, risks, and benefits of a new activity; and (2) Determine whether the new activity is a new product that merits public notice and comment. Sufficient information is needed to have a complete assessment and understanding of associated risks to support adequate oversight and control, and to weigh those risks against the benefits to public interest. Should FHFA determine that a new activity is a new product that merits public notice and comment, the content of the Notice of New Activity will also provide the public the information it needs to review and meaningfully comment on the proposed new product.

In the Interim Final Rule, the content for a Notice of New Activity is set forth in a form in the Appendix to 12 CFR part 1253, which includes instructions for providing the required content. The Appendix also includes additional general and supplemental instructions to aid the Enterprise in identifying an activity and new product, and to complete the form.

In the proposed rule, FHFA seeks to streamline and simplify the content and submission of a Notice of New Activity by incorporating the content into the regulation text rather than in a specific form as part of an appendix to the regulation. This approach also allows for more flexibility in how the information is submitted by an Enterprise and received by FHFA. Requiring a static form might be inconsistent with the most effective means for the Enterprise to present data, images, or other information. The proposed rule also consolidates interrelated content from the sets of instructions in the Interim Final Rule for clarity and to reduce duplication.

For example, the Interim Final rule requires a separate description of unusual and unique characteristics of the new activity (Interim Final Rule, 12 CFR part 1253, Notice of New Activity Form, Item 3), which FHFA would expect an Enterprise to describe under the requirement for a complete and specific description of the new activity under proposed § 1253.9(a)(2). Another area of consolidation in the proposed rule involves the information that must be provided on the business requirements for a new activity, which includes a description of the technology requirements, the business unit(s) involved and reporting lines, as well as any affiliation or subsidiary relationships, any third-party relationships, and the roles of each. In the Interim Final Rule there are three distinct items on the form requiring a

description of: (1) The business unit(s) and responsible personnel for the new activity (Item 5); (2) Relationships with non-secondary market participants (Item 9); and (3) Whether an acquisition by an Enterprise is involved with the new activity (Item 11). FHFA believes that streamlining the content of a Notice of New Activity will facilitate an Enterprise's compliance with the requirements of the regulation without impeding FHFA's ability to determine whether a new activity is a new product that merits public notice and comment.

7. *FHFA requests comment on the content of a Notice of New Activity, specifically whether the requirements are clearly stated and sufficient for evaluating a New Activity.*

8. *FHFA requests comment on whether it should retain a pdf form for the Notice of New Activity similar to the form included in the Appendix to the Interim Final Rule.*

H. Preservation of Authority

Section 1253.10 of the propose rule would confirm that the Director's authority is preserved. The Director's exercise of the Safety and Soundness Act's provisions on prior approval authority for products in no way restricts the safety and soundness authority of the Director over all new and existing products or activities, or the authority of the Director to review all new and existing products or activities to determine that such products or activities are consistent with the statutory mission of an Enterprise. *See* section 1321(f) of the Safety and Soundness Act (12 U.S.C. 4541(f)). Under this authority, for example, the Director could find that certain conditions or terms are appropriate for an ongoing activity. This section would also inform the Enterprise that failure to comply with the provisions of this regulation may result in FHFA requiring the Enterprise to submit a Notice of New Activity subject to the review and approval requirements of this section, without regard to whether the Enterprise has already commenced such activity, or taking enforcement actions, including pursuant to 12 U.S.C. 4631 (orders to cease-and-desist), 12 U.S.C. 4632 (temporary orders to cease-and-desist), and 12 U.S.C. 4636 (civil money penalties), or other steps authorized by law.

9. *FHFA requests comment on aspects of the proposed Prior Approval for Enterprise Products rule that are changes or deletions from the Interim Final Rule.*

10. *In addition to the questions asked above, FHFA requests comments on any aspect of the proposed Prior Approval for Enterprise Products rule.*

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq*) requires that a regulation that has a significant economic impact on a substantial number of small entities, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. Such an analysis need not be undertaken if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities (5 U.S.C 605(b)). FHFA has considered the impact of the proposed rule under the Regulatory Flexibility Act. The General Counsel of FHFA certifies that the proposed rule, if adopted as a final rule, will not have a significant economic impact on a substantial number of small entities because the regulation only applies to Fannie Mae and Freddie Mac, which are not small entities for purposes of the Regulatory Flexibility Act.

V. Paperwork Reduction Act

The proposed rule does not contain any information collection requirement that requires the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

List of Subjects in 12 CFR Part 1253

Government-sponsored enterprises, Mortgages, New activities, New products.

Authority and Issuance

Accordingly, for the reasons stated in the preamble, under the authorities of 12 U.S.C. 4526 and 12 U.S.C. 4541, FHFA proposes to amend Chapter XII of Title 12, Code of Federal Regulations as follows:

CHAPTER XII—FEDERAL HOUSING FINANCE AGENCY

Subchapter C—Enterprises

■ 1. Revise part 1253 to read as follows:

PART 1253—PRIOR APPROVAL FOR ENTERPRISE PRODUCTS

Sec.

1253.1 Purpose and authority.
1253.2 Definitions.
1253.3 New Activity description and exclusions.
1253.4 New Product.
1253.5 Review of Notice of New Activity.
1253.6 New Product approval.
1253.7 Temporary approval of a New Product.
1253.8 Availability of an approved New Product and substantially similar approved New Product to the other Enterprise.
1253.9 Notice of New Activity.
1253.10 Preservation of authority.

Authority: 12 U.S.C. 4526; 12 U.S.C. 4541.

§ 1253.1 Purpose and authority.

The purpose of this part is to establish policies and procedures implementing the prior approval authority for Enterprise products, in accordance with section 1321 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4541), as amended (Safety and Soundness Act).

§ 1253.2 Definitions.

For purposes of this part:

Authorizing statute means the Federal National Mortgage Association Charter Act and the Federal Home Loan Mortgage Corporation Act, as applicable.

Credit risk is the potential that a borrower or counterparty will fail to meet its obligations in accordance with agreed terms. Credit risk includes the decline in measured quality of a credit exposure that might result in increased capital costs, provisioning expenses, and a reduction in economic return.

Days means calendar days.

Market risk means the risk that the market value, or estimated fair value if the market value is not available, of a regulated entity's portfolio will decline as a result of changes in interest rates, foreign exchange rates, or equity or commodity prices.

New Activity has the meaning provided in § 1253.3.

New Product has the meaning provided in § 1253.4.

Operational risk means the risk of loss resulting from inadequate or failed internal processes, people, or systems, or from external events, including all direct and indirect economic losses related to legal liability. This includes reputational risk, which is the potential for substantial negative publicity regarding an institution's business practices.

Pilot means an activity that has a defined term and scope for purposes of understanding the viability of a new offering. A pilot may also be referred to as testing initiative, test and learn, temporary authorization, or other names.

§ 1253.3 New Activity description and exclusions.

(a) A New Activity is an activity that meets the requirements of this section:

(1) An activity which is a business line, business practice, offering or service, including guarantee, financial instrument, consulting or marketing,

that the Enterprise provides to the market either on a standalone basis or as part of a business line, business practice, offering or service; and

(2) An activity which:

(i) Is not engaged in by the Enterprise as of the effective date of this section, or (ii) Is an enhancement, alteration, or modification to an existing activity that the Enterprise currently engages in as of the effective date of this section; and

(3) An activity that is described by one or more of the following paragraphs:

(i) Activity which requires one or more of the following: a new type of resource, a new type of data, a new policy or modification to an existing policy, a new process or infrastructure.

(ii) Activity that expands the scope or increases the level of credit risk, market risk or operational risk to the Enterprise.

(iii) Activity that involves a new category of borrower, investor, counterparty, or collateral.

(iv) Activity that would substantially impact the mortgage finance system, safety and soundness of the Enterprise, compliance with the Enterprise's authorizing statute, or the public interest as identified in § 1253.4(b).

(v) Activity that is a pilot.

(vi) Activity resulting from a pilot that is described by one or more of paragraphs (a)(3)(i) through (iv) of this section.

(b) A New Activity excludes an activity which is described as:

(1) The automated loan underwriting system of an Enterprise, including any upgrade to the technology, operating system, or software to operate the underwriting system.

(2) Any modification to the mortgage terms and conditions or mortgage underwriting criteria relating to the mortgages that are purchased or guaranteed by an Enterprise, provided that such modifications do not alter the underlying transaction so as to include services or financing, other than residential mortgage financing.

(3) Any activity that is substantially similar to the activities described in paragraph (b)(1) or (2) of this section. If the activity is described by one or more of paragraphs (a)(3)(i) through (iv) of this section, the activity is not substantially similar and the Enterprise must submit a Notice of New Activity for review under the provisions of this section and may not proceed with the New Activity except pursuant to the requirements in this section.

(4) Pursuant to the requirements of § 1253.8, any activity undertaken by an Enterprise that is the same as, or substantially similar to, a New Product that the Director has approved for the other Enterprise under § 1253.6(a) through (e), or a New Product that is otherwise available to the other Enterprise under § 1253.6(g).

(5) Any Enterprise business practice, transactions, or conduct performed solely to facilitate the administration of an Enterprise's internal affairs to conduct its business.

§ 1253.4 New Product.

(a) A New Product is any New Activity that the Director determines merits public notice and comment about whether it is:

(1) In the case of Fannie Mae, authorized under 12 U.S.C. 1717(b)(2), (3), (4), or (5) or 12 U.S.C. 1719; or

(2) In the case of Freddie Mac, authorized under 12 U.S.C. 1454(a)(1), (4), or (5); and

(3) In the public interest; and

(4) Consistent with the safety and soundness of the Enterprise or the mortgage finance system.

(b) The factors that the Director may consider when determining whether a New Product is in the public interest are:

(1) The degree to which the New Product might advance any of the purposes of the Enterprise under its authorizing statute;

(2) The degree to which the New Product serves underserved markets and housing goals as set forth in section 1335 of the Safety and Soundness Act (12 U.S.C. 4565);

(3) The degree to which the New Product is being or could be supplied by other market participants;

(4) The degree to which the New Product promotes competition in the marketplace or, to the contrary, would result in less competition;

(5) The degree to which the New Product overcomes natural market barriers or inefficiencies;

(6) The degree to which the New Product might raise or mitigate systemic risks to the mortgage finance or financial system;

(7) The degree to which the New Product furthers fair housing and fair lending; and

(8) Such other factors as determined appropriate by the Director.

§ 1253.5 Review of Notice of New Activity.

(a) Before commencing a New Activity, an Enterprise must submit a Notice of New Activity to FHFA. FHFA will evaluate the Notice of New Activity to determine if the submission contains sufficient information for the Director to make a determination whether the New Activity is a New Product subject to prior approval. In support of its Notice of New Activity, the Enterprise shall submit information as described under § 1253.9. The Enterprise shall provide thorough, complete, and specific information such that the public will be able to provide fully informed comments if the Director determines the New Activity to be a New Product. Once FHFA makes the determination that the submission is complete, FHFA will notify the Enterprise that the submission is ''received'' for purposes of 12 U.S.C. 4541(e)(2)(B).

(b) Nothing in this regulation limits or restricts FHFA from reviewing a Notice of New Activity under any other applicable law, under the Director's authority to review for safety and soundness, or to determine whether the activity complies with the Enterprise's authorizing statute. FHFA may conduct such a review as part of its determination that the Notice of New Activity submission is complete.

(c) No later than 15 days after FHFA notifies the Enterprise that the submission is received, the Director will make a determination on the Notice of New Activity and will notify the Enterprise accordingly. If the Director determines that the New Activity is a New Product, the Enterprise must await approval or disapproval of the New Product under § 1253.6.

(d) If the Director determines that the New Activity is not a New Product, or if after passage of 15 days the Director does not make a determination whether the New Activity is a New Product, the Enterprise may commence the New Activity. The Director may establish terms, conditions, or limitations on the Enterprise's engagement in the New Activity as the Director determines to be appropriate and with which the Enterprise must comply in order to engage in the New Activity.

(e) If the Director does not make a determination within the 15-day period, the absence of such determination does not limit or restrict the Director's safety and soundness authority or the Director's authority to review the New Activity to determine that the activity is consistent with the Enterprise's authorizing statute.

§ 1253.6 New Product approval.

(a) If the Director determines that the New Activity is a New Product, FHFA shall publish a public notice soliciting comments on the New Product for a 30-day period.

(1) The public notice will describe the New Product. FHFA will include such information from the Notice of New Activity as to provide the public with sufficient information to comment on the New Product. The public notice will state the closing date of the public comment period and will provide

instructions for submission of public comment.

(2) The Director will consider all public comments received by the closing date of the comment period.

(3) In computing the 30-day public comment period, FHFA includes the day on which the public notice is published, from which the period commences, and includes the last day of the period, regardless of whether it is a Saturday, Sunday, or legal holiday.

(b) No later than 30 days after the end of the public comment period, the Director will provide the Enterprise with a written determination on whether it may proceed with the New Product. The written determination will specify the grounds for the Director's determination.

(c) The Director may approve the New Product if the Director determines that the New Product:

(1) In the case of Fannie Mae, is authorized under 12 U.S.C. 1717(b)(2), (3), (4), or (5) or 12 U.S.C. 1719; or

(2) In the case of Freddie Mac, is authorized under 12 U.S.C. 1454(a)(1), (4), or (5); and

(3) Is in the public interest; and

(4) Is consistent with the safety and soundness of the Enterprise or the mortgage finance system.

(d) The Director may consider factors provided in § 1253.4(b) when determining whether a New Product is in the public interest.

(e) The Director may establish terms, conditions, or limitations on the Enterprise's offering of the New Product with which the Enterprise must comply in order to offer the New Product.

(f) If the Director disapproves the New Product, the Enterprise may not offer the New Product.

(g) If the Director does not make a determination within 30 days after the end of the public comment period, the Enterprise may offer the New Product. The absence of such a determination within 30 days does not limit or restrict the Director's safety and soundness authority or the Director's authority to review the New Product to determine that the product is consistent with the Enterprise's authorizing statute.

(h) The Director may request any information in addition to that supplied in the completed Notice of New Activity if, as a result of public comment or otherwise in the course of considering the Notice of New Activity, the Director believes that the information is necessary for the Director's decision. The Director may disapprove a New Product if the Director does not receive the information requested from the Enterprise in sufficient time to permit adequate evaluation of the information within the time periods set forth in this section.

§ 1253.7 Temporary approval of a New Product.

The Director may approve a New Product without first seeking public comment as described in § 1253.6 if:

(a) The Enterprise submits a specific request for Temporary Approval that describes the exigent circumstances that make the delay associated with a 30-day public comment period contrary to the public interest and the Director determines that exigent circumstances exist and that delay associated with first seeking public comment would be contrary to the public interest; or

(b) Notwithstanding the absence of a request by the Enterprise for Temporary Approval, the Director determines on the Director's own initiative that there are exigent circumstances that make the delay associated with first seeking public comment contrary to the public interest.

(c) The Director may impose terms, conditions, or limitations on the Temporary Approval to ensure that the New Product offering is consistent with the factors in § 1253.6(c).

(d) If the Director grants Temporary Approval, the Director will notify the Enterprise in writing of the Director's decision and include the period for which it is effective and any terms, conditions or limitations. Upon granting of Temporary Approval, FHFA will also publish the request for public comment to begin the process for permanent approval.

(e) If the Director denies a request for Temporary Approval, the Director will notify the Enterprise in writing of the Director's decision and will evaluate the New Product in accordance with this section.

§ 1253.8 Availability of an approved New Product and substantially similar approved New Product to the other Enterprise.

(a) Either Enterprise may offer a New Product that the Director has approved for the other Enterprise under § 1253.6(a) through (e), or a New Product that is otherwise available to the other Enterprise under § 1253.6(g).

(1) An Enterprise shall notify FHFA of its intent to begin offering the New Product at least 15 days prior to offering the New Product.

(2) The notification is not required to be a Notice of New Activity. The notification shall include the name of the New Product and a complete and specific description.

(3) Public notice and comment is not required in connection with this offering.

(b) Either Enterprise may offer an activity that is substantially similar to a New Product that the Director has approved for the other Enterprise under § 1253.6(a) through (e), or a New Product that is otherwise available to the other Enterprise under § 1253.6(g).

(1) An Enterprise shall notify FHFA of its intent to begin offering the activity that is substantially similar to the New Product at least 15 days prior to offering the activity that is substantially similar to the New Product.

(2) The notification is not required to be a Notice of New Activity. The notification shall include the name of the activity that is substantially similar to the New Product and a complete and specific description. The notification shall include a description of why the Enterprise believes the activity is substantially similar to the New Product.

(3) Public notice and comment is not required in connection with this offering.

(4) If the activity is described by one or more of the paragraphs at § 1253.3(a)(3)(i) through (iv), the Director may determine that the activity is not substantially similar. If the Director determines an activity is not substantially similar, the Enterprise must submit a Notice of New Activity for review under the provisions of this section and may not proceed with the New Activity except pursuant to the requirements in this section.

§ 1253.9 Notice of New Activity.

(a) A Notice of New Activity must provide the following items of information and provide appropriate supporting documentation. The corresponding paragraph number should be listed with the relevant information provided:

(1) Name of the New Activity.

(2) Complete and specific description of the New Activity.

(3) Identify under which paragraphs of § 1253.3 the New Activity is described.

(4) State the Enterprise's view as to whether the New Activity is a New Product.

(5) Describe the business rationale, the intended market, the business line, and what products are currently being offered or propose to be offered under such business line.

(6) State the anticipated commencement date, and duration, for the New Activity or New Product. Describe and provide analysis, including assumptions, development expenses, any applicable fees, expectations for the impact of and projections for the projected quarterly

size (for example, in terms of cost, personnel, volume of activity, or risk metrics) of the New Activity or New Product for at least the first 12 months of deployment. If the New Activity is a pilot, include the parameters that end the pilot, such as duration, volume of activity, and performance. If the New Activity is the result of a pilot, include an analysis on the effectiveness of the pilot that describes the pilot objectives and success criteria; volume of activity; performance; risk metrics and controls; and the modifications made for a broader offering and rationale. Describe any market research performed relating to the New Activity or New Product.

(7) Describe, explain and provide analysis, including assumptions, expectations for the impact of, and projections for the anticipated impact to earnings and capital of the New Activity or New Product on a quarterly basis for the first 12 months from the New Activity or New Product's commencement.

(8) Describe the impact of the New Activity or New Product on the risk profile of the Enterprise. Describe key controls for the following risks: credit, market and operational.

(9) Describe the business requirements for the New Activity or New Product including technology requirements. Describe the Enterprise business units involved in conducting the New Activity or New Product, including any affiliation or subsidiary relationships, any third-party relationships, and the roles of each. Describe the reporting lines and planned oversight of the New Activity or New Product.

(10) Provide a fair lending self-evaluation of the New Activity or New Product. The fair lending self-evaluation should, at a minimum, include data on the predicted impact of the New Activity or New Product for protected class categories if such an impact is expected, a summary of reasonable alternatives considered, and, if applicable, the business justification for the New Activity or New Product.

(11) Provide an analysis and legal opinions as to whether the New Activity is a New Product and whether it is:

(i) In the case of Fannie Mae, authorized under 12 U.S.C. 1717(b)(2), (3), (4), or (5) or 12 U.S.C. 1719; or

(ii) In the case of Freddie Mac, authorized under 12 U.S.C. 1454(a)(1), (4), or (5).

(12) Provide copies of all notice and application documents, including any application for patents or trademarks, the Enterprise has submitted to other federal, state or local government regulators relating to a New Activity or New Product.

(13) Describe the impact of the New Activity or New Product on the public interest and provide information to address the factors listed in § 1253.4(b).

(14) Describe how the New Activity or New Product is consistent with the safety and soundness of the Enterprise and the mortgage finance system.

(15) Explain any accounting treatment proposed for the New Activity and New Product.

(b) FHFA may require an Enterprise to submit such further information as the Director deems necessary to review the submission or to make a determination, at the time of the original submission or anytime thereafter.

(c) An Enterprise shall certify, through an executive officer, that any filing or supporting material submitted to FHFA pursuant to regulations in this part contains no material misrepresentations or omissions. FHFA may review and verify any information filed in connection with a Notice of New Activity.

§ 1253.10 Preservation of authority.

(a) The Director's exercise of the Director's authority pursuant to the prior approval authority for products under 12 U.S.C. 4541, and this regulation, in no way restricts:

(1) The safety and soundness authority of the Director over all new and existing products or activities; or

(2) The authority of the Director to review all new and existing products or activities to determine that such products or activities are consistent with the authorizing statute of an Enterprise.

(b) Failure to comply with the provisions of this section may result in any of the following actions:

(1) FHFA may require the Enterprise to submit a Notice of New Activity subject to the review and approval requirements of this section, without regard to whether the Enterprise has already commenced such activity;

(2) FHFA may take enforcement actions, including pursuant to 12 U.S.C. 4631 (orders to cease-and-desist), 12 U.S.C. 4632 (temporary orders to cease-and-desist), and 12 U.S.C. 4636 (civil money penalties); and

(3) FHFA may take any other steps authorized by law to address the Enterprise's failure to comply.

Mark A. Calabria,

Director, Federal Housing Finance Agency.

[FR Doc. 2020–23452 Filed 11–6–20; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0985; Product Identifier 2018–SW–064–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH

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 Helicopters Deutschland GmbH Model EC135P1, EC135T1, EC135P2, EC135T2, EC135P2+, EC135T2+, EC135P3, and EC135T3 helicopters. This proposed AD was prompted by a deviation from a new manufacturing process, which resulted in a reduced life limit (service life limit) for certain tail rotor blades. This proposed AD would require a reduced life limit for those tail rotor blades and require a new life limit for certain other tail rotor blades, as specified in a European 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 December 24, 2020.

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

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

For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; 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–2020–0985.

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–2020–0985; 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:

Kristin Bradley, Aviation Safety Engineer, International Validation Branch, General Aviation & Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5485; email *Kristin.Bradley@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one copy of the comments. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA 2020–0985; Product Identifier 2018–SW–064–AD'' at the beginning of your 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, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

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 Kristin Bradley, Aviation Safety Engineer, International Validation Branch, General Aviation & Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5485; email *Kristin.Bradley@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 (now European Union Aviation Safety Agency), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0168, dated July 27, 2018 (EASA AD 2018–0168) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus Helicopters Deutschland GmbH Model EC135 P1, EC135 P2, EC135 P2+, EC135 P3, EC135 T1, EC135 T2, EC135 T2+, EC135 T3, EC635 P2+, EC635 P3, EC635 T1, EC635 T2+ and EC635 T3 helicopters. Model EC635 P2+, EC635 P3, EC635 T1, and EC635 T3 helicopters are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this proposed AD therefore does not include those helicopters in the applicability. Model EC635 T2+ helicopters are also not certificated by the FAA and are not included on the U.S. type certificate data sheet except where the U.S. type certificate data sheet explains that the Model EC635T2+ helicopter having serial number 0858 was converted from Model EC635T2+ to Model EC135T2+; this proposed AD therefore does not include Model EC635 T2+ helicopters in the applicability.

This proposed AD was prompted by a deviation from a new manufacturing process, which resulted in a reduced life limit (service life limit) for certain tail rotor blades. The FAA is proposing this AD to address a tail rotor blade remaining in service beyond its life limit, which could result in failure of that tail rotor blade and subsequent loss of control of the helicopter. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2018–0168 requires a reduced service life of certain tail rotor blades and requires a new service life limit for certain other tail rotor blades (affected parts that have been re-identified).

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 2018–0168, 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 2018–0168 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2018–0168 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 2018–0168 that is required for compliance with EASA AD 2018–0168 will be available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0985 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 345 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
1 work-hour × $85 per hour = $85	$3,900	$3,985	$1,374,825

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 Deutschland GmbH: Docket No. FAA–2020–0985; Product Identifier 2018–SW–064–AD.

(a) Comments Due Date

The FAA must receive comments by December 24, 2020.

(b) Affected Airworthiness Directives (ADs)

None.

(c) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH Model EC135P1, EC135T1, EC135P2, EC135T2, EC135P2+, EC135T2+, EC135P3, and EC135T3 helicopters, certificated in any category, equipped with a tail rotor blade identified as an affected part in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2018–0168, dated July 27, 2018 (EASA AD 2018–0168).

(d) Subject

Joint Aircraft System Component (JASC) Code 6410, Tail Rotor Blades.

(e) Reason

This AD was prompted by a deviation from a new manufacturing process, which resulted in a reduced life limit (service life limit) for certain tail rotor blades. The FAA is issuing this AD to address a tail rotor blade remaining in service beyond its life limit, which could result in failure of that tail rotor blade and subsequent 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, EASA AD 2018–0168.

(h) Exceptions to EASA AD 2018–0168

(1) Where EASA AD 2018–0168 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2018–0168 does not apply to this AD.

(3) Where EASA AD 2018–0168 refers to flight hours (FH), this AD requires using hours time-in-service.

(i) 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; telephone 817–222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(j) Related Information

(1) For EASA AD 2018–0168, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; 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–2020–0985.

(2) For more information about this AD, contact Kristin Bradley, Aviation Safety Engineer, International Validation Branch, General Aviation & Rotorcraft Unit, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817 222 5485; email *Kristin.Bradley@faa.gov.*

Issued on November 2, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–24766 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0925; Airspace Docket No. 20–ANM–18]

RIN 2120–AA66

Proposed Amendment of Class D and Class E Airspace; Tacoma Narrows Airport, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class D airspace, Class E surface Airspace and Class E airspace extending upward from 700 feet above ground level (AGL) at Tacoma Narrows Airport, Tacoma, WA. A review of the airspace was initiated due to corresponding reviews at McChord Field (Joint Base Lewis-McChord) and Gray AAF (Joint Base Lewis-McChord). All three locations were evaluated at the same time due to their close proximity to one another and operational interdependence. After a review of the airspace, the FAA found it necessary to amend the existing airspace for the safety and management of Instrument Flight Rules (IFR) operations at this airport.

DATES: Comments must be received on or before December 24, 2020.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–0925; Airspace Docket No. 20–ANM–18, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the Class D airspace, Class E surface airspace and Class E airspace extending upward from 700 feet above ground level to support IFR operations at Tacoma Narrows Airport, Tacoma, WA.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2020–0925; Airspace Docket No. 20–ANM–18''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

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

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

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying the lateral boundaries of the Class D and Class E surface airspace and the Class E airspace extending upward from 700 feet AGL at Tacoma Narrows Airport,

Tacoma, WA. A review of the airspace was initiated due to corresponding reviews at McChord Field (Joint Base Lewis-McChord) and Gray AAF (Joint Base Lewis-McChord). All three locations were evaluated at the same time due to their close proximity to one another and operational interdependence. The airspace at McChord Field and Gray AAF (Joint Base Lewis-McChord) were reviewed due to three actions. The FAA decommissioned the McChord VORTAC because the U.S. Air Force was no longer going to maintain the NAVAID. The U.S. Air Force requested elimination of previously excluded airspace, which required an airspace review to evaluate that request and the Class D airspace at McChord Field and Gray AAF (Joint Base Lewis-McChord) had not been examined in the previous two years, as required by FAA Orders.

The Tacoma Narrows Airport Class D and Class E surface airspace that extends to 5.3 miles south of the airport would be removed as it is no longer needed for arrivals or departures.

In addition, the Class E airspace extending upward from 700 feet AGL within 4 miles each side of the 007° and 187° bearings from the Tacoma Narrows Airport extending to 8 miles north and 7 miles south of the airport will be shortened to 6 miles, respectively.

Class D and Class E airspace designations are published in paragraph 5000, 6002, 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR part 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in the Order.

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

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR Part 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANM WA D Tacoma, WA [Amended]

Tacoma Narrows Airport, WA
(Lat. 47°16′05″ N, long. 122°34′41″ W)

McChord Field (Joint Base Lewis-McChord), WA
(Lat. 47°08′17″ N, long. 122°28′34″ W)

That airspace extending upward from the surface to and including 2,800 feet MSL within a 4-mile radius of Tacoma Narrows Airport, excluding that airspace within the McChord Field (Joint Base Lewis-McChord) Class D airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

ANM WA E2 Tacoma, WA [Amended]

Tacoma Narrows Airport, WA
(Lat. 47°16′05″ N, long. 122°34′41″ W)

McChord Field (Joint Base Lewis-McChord), WA
(Lat. 47°08′17″ N, long. 122°28′34″ W)

That airspace extending upward from the surface within a 4-mile radius of Tacoma Narrows Airport, excluding that airspace within the McChord Field (Joint Base Lewis-McChord) Class D airspace area. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM WA E5 Tacoma, WA [Amended]

Tacoma Narrows Airport, WA
(Lat. 47°16′05″ N, long. 122°34′41″ W)

That airspace extending upward from 700 feet above the surface within 4 miles each side of the 007° bearing from the Tacoma Narrows Airport extending to 6 miles north of the airport, and within 4 miles each side of a 187° bearing from the airport extending to 6 miles south of the airport.

Issued in Seattle, Washington, on November 2, 2020.

Byron Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2020–24751 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0899; Airspace Docket No. 20–ANM–16]

RIN 2120–AA66

Proposed Modification of Class D Airspace; Gray AAF (Joint Base Lewis-McChord), WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class D airspace at Gray AAF (Joint Base Lewis-McChord), Fort Lewis/Tacoma, WA. After a review of the airspace, the FAA found it necessary to amend the existing airspace for the safety and management of Instrument Flight Rules (IFR) operations at this airport. This proposal would also remove a reference to the McChord VORTAC from the legal description, update the airport name and city, and amend the geographical coordinates for the airport to match the FAA's database.

DATES: Comments must be received on or before December 24, 2020.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–0899; Airspace Docket No. 20–ANM–16, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the Class D airspace to support IFR operations at Gray AAF (Joint Base Lewis-McChord), Fort Lewis/Tacoma, WA.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2020–0899; Airspace Docket No. 20–ANM–16''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

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

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

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying the lateral dimensions of the Class D airspace. The FAA initiated a review of the assigned airspace and drafted the subsequent proposal for modification due to two actions. The FAA decommissioned the McChord VORTAC because the U.S. Air Force was no longer going to maintain the NAVAID. As a result of the decommissioning, the FAA was required to redefine airspace that uses the VORTAC as a reference and remove the references from the associated airspace descriptions. The Class D airspace had not been examined in the previous two years, as required by FAA Orders.

The Class D airspace lateral boundary would be established within a 4 mile radius of the airport instead of a 4.3 mile radius. The additional airspace was no longer needed.

In addition, the name and city of the airport and the geographical coordinates for Gray AAF (Joint Base Lewis-McChord) would be updated to match the FAA's National Airspace System Resource (NASR) database.

Class D airspace designations are published in paragraph 5000 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR part 71.1. The Class D airspace designations listed in this document will be published subsequently in the Order.

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

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it

is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR Part 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANM WA D Fort Lewis/Tacoma, WA (Amend)

Gray AAF (Joint Base Lewis-McChord), WA
(Lat. 47°04′45″ N, long. 122°34′51″ W)

McChord Field (Joint Base Lewis-McChord), WA
(Lat. 47°08′17″ N, long. 122°28′35″ W)

That airspace extending upward from the surface to and including 2,800 feet MSL within a 4-mile radius of Gray AAF, excluding the portions within the McChord Field (Joint Base Lewis-McChord) Class D airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Issued in Seattle, Washington, on October 29, 2020.

Byron Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2020–24581 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0941; Airspace Docket No. 20–ASO–24]

RIN 2120–AA66

Proposed Amendment and Cancellation of VOR Federal Airways V–49 and V–541 in the Vicinity of Decatur, AL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify VHF Omni-directional Range (VOR) Federal airway V–541 and remove V–49, in the vicinity of Decatur, AL. This action is necessary due to the planned decommissioning of the Decatur, AL, VOR/Distance Measuring Equipment (DME) navigation aid, which provides navigation guidance for segments of the routes. This proposal would provide for the safe and efficient use of navigable airspace within the National Airspace System (NAS) while reducing NAVAID dependencies throughout the NAS as part of the FAA VOR Minimum Operation Network program.

DATES: Comments must be received on or before December 24, 2020.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1 (800) 647–5527 or (202) 366–9826. You must identify FAA Docket No. FAA–2020–0941 and Airspace Docket No. 20–ASO–24 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov,* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2020–0941 and Airspace Docket No. 20–ASO–24) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following

statement is made: ''Comments to FAA Docket No. FAA–2020–0941 and Airspace Docket No. 20–ASO–24.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRM's

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

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020 and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this proposed rule. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to modify VOR Federal airway V–541 and remove V–49, in the vicinity of Decatur, AL, due to the planned decommissioning of the Decatur, AL, VOR/DME as part of the FAA VOR Minimum Operation Network program. The proposed route changes are described below.

V–49: V–49 currently extends from the Vulcan, AL, VORTAC to the Nashville, TN, VORTAC. The FAA proposes to remove the entire route.

V–541: V–541 currently extends from the Gadsden, AL, VOR/DME to the Muscle Shoals, AL, VORTAC. The FAA proposes to straighten V–541 from the Gadsden VOR to the EDDIE intersection and remove the portion from the EDDIE intersection (INT Gadsden 318° T/316° M and Vulcan, AL, 029° T/027° M radials) to the Muscle Shoals VORTAC. This will eliminate the dogleg that currently exists at AWPOJ, which is a Computer Notification Fix.

Note: In the V–541 description, both True (T) and Magnetic (M) degrees are stated because new radials are being used in the legal description (EDDIE intersection) to replace AWPOJ intersection (INT Gadsden 318° and Decatur, AL, 130° radials).

Domestic VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airways listed in this document would be subsequently published in the Order.

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

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020 and effective September 15, 2020, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–49 [Removed]

* * * * *

V–541 [Amended]

From Gadsden, AL, to INT Gadsden 318° T/316° M and Vulcan, AL, 029° T/027° M radials.

* * * * *

Issued in Washington, DC, on October 30, 2020.

George Gonzalez,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–24804 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0923; Airspace Docket No. 20–AEA–18]

RIN 2120–AA66

Proposed Amendment, Establishment, and Revocation of Multiple Air Traffic Service (ATS) Routes in the Vicinity of Henderson, WV

Correction

In proposed rule document 2020–24288 beginning on page 70093 in the issue of Wednesday, November 4, 2020, make the following correction:

■ 1. On page 70095, in the third column, beginning in the 25th line, amendatory instruction 2 is corrected to read as follows:

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–91 [Removed]

* * * * *

J–134 [Amended]

From Los Angeles, CA; Seal Beach, CA; Thermal, CA; Parker, CA; Drake, AZ; Gallup, NM; Cimarron, NM; Liberal, KS; Wichita, KS; Butler, MO; St Louis, MO; to Falmouth, KY.

* * * * *

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q–67 SMTTH, TN to Henderson, WV (HNN) [Amended]

SMTTH, TN WP (Lat. 35°54′41.57″ N, long. 084°00′19.74″ W)
TONIO, KY FIX (Lat. 37°15′15.20″ N, long. 083°01′47.53″ W)
Henderson, WV (HNN) DME (Lat. 38°45′14.85″ N, long. 082°01′34.20″ W)

* * * * *

Q–176 Cimarron, NM (CIM) to OTTTO, VA [New]

Cimarron, NM (CIM) VORTAC (Lat. 36°29′29.03″ N, long. 104°52′19.20″ W)
KENTO, NM WP (Lat. 36°44′19.10″ N, long. 103°05′57.13″ W)
Liberal, KS (LBL) VORTAC (Lat. 37°02′39.82″ N, long. 100°58′16.31″ W)
Wichita, KS (ICT) VORTAC (Lat. 37°44′42.92″ N, long. 097°35′01.79″ W)
Butler, MO (BUM) VORTAC (Lat. 38°16′19.49″ N, long. 094°29′17.74″ W)
St Louis, MO (STL) VORTAC (Lat. 38°51′38.48″ N, long. 090°28′56.52″ W)
GBEES, IN FIX (Lat. 38°41′54.72″ N, long. 085°10′13.03″ W)
BICKS, KY WP (Lat. 38°38′29.92″ N, long. 084°25′20.82″ W)
Henderson, WV (HNN) DME (Lat. 38°45′14.85″ N, long. 082°01′ 34.20″ W)
OTTTO, VA WP (Lat. 38°51′15.81″ N, long. 078°12′20.01″ W)

* * * * *

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–45 [Amended]

From New Bern, NC; Kinston, NC; Raleigh-Durham, NC; INT Raleigh-Durham 275° and Greensboro, NC, 105° radials; Greensboro; INT Greensboro 334° and Pulaski, VA, 147° radials; Pulaski; Bluefield, WV; to Charleston, WV. From Saginaw, MI; Alpena, MI; to Sault Ste Marie, MI.

* * * * *

V–119 [Amended]

From Parkersburg, WV; INT Parkersburg 067° and Indian Head, PA, 254° radials; Indian Head; to Clarion, PA.

* * * * *

V–174 [Removed]

* * * * *

[FR Doc. C1–2020–24288 Filed 11–6–20; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA–2020–N–1119]

Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States; Extension of Comment Period

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notification entitled ''Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States'' that appeared in the **Federal Register** of August 10, 2020. We are taking this action in response to a request from stakeholders to extend the comment period to allow additional time for interested persons to develop and submit data, information, and/or comments for this Request for Information.

DATES: FDA is extending the comment period on the Request for Information published August 10, 2020 (85 FR 48124). Submit either electronic or written comments by January 8, 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 January 8, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 8, 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–2020–N–1119 for ''Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States.'' 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: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 10, 2020 (85 FR 48124), we published a notification entitled ''Request for Information and Comments on Consumption of Certain Uncommon Produce Commodities in the United States.'' This action opened a docket with a 90-day comment period to receive information and comments related to certain produce commodities with no or low reported consumption in the database relied on to create the list of rarely consumed raw commodities that are exempt from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 CFR part 112) (produce safety regulation).

FDA has received a request for a 60-day extension for this comment period in order to allow additional time for interested persons to develop and submit data, information, and/or comments for this Request for Information. We have concluded that it is reasonable to extend for 60 days the comment period for this Request for Information. The Agency believes that this extension allows adequate time for any interested persons to submit data, information, and/or comments for this Request for Information.

Dated: November 3, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–24806 Filed 11–6–20; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2008–0784; FRL–10011–77–Region 5]

Air Plan Approval; Wisconsin; PSD and Nonattainment NSR Rule Clarifications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Wisconsin state implementation plan (SIP), submitted by the Wisconsin Department of Natural Resources (WDNR) on September 30, 2008. The revision updates the definition of ''Replacement Unit'' and clarifies a component of the emission calculation used to determine emissions under a plantwide applicability limitation (PAL) in the Wisconsin Administrative Code. Approving this revision makes Wisconsin rules consistent with Federal rules.

DATES: Comments must be received on or before December 9, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2008–0784 at *http://www.regulations.gov,* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Cloyd, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312)886–1474, *Cloyd.Michael@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID 19.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. Review of Wisconsin's Submittal

This action proposes to approve the request EPA received on September 30, 2008 from WDNR to incorporate changes made by EPA to 40 CFR parts 51 and 52, effective on January 6, 2004 (68 FR 63021). As a result of petitions for reconsideration, EPA added two clarifications of underlying rules. EPA updated the definition of ''Replacement Unit'' to clarify that a replacement unit is reconstructed or takes the place completely of the unit being replaced, the replacement unit is functionally identical to the old unit, a replacement unit cannot change the design parameters of the existing process, and the replaced unit has to be permanently removed or rendered permanently unusable. In addition, EPA clarified that the PAL baseline calculation procedures for newly constructed units do not apply to modified units. Modified or existing units are not considered newly constructed units and therefore do not need to be added to the PAL level for the 24-month emissions period.

Wisconsin's submittal includes revisions to its SIP to incorporate these changes. Wisconsin's rules are consistent with the January 6, 2004 definition of ''Replacement Unit'' and clarification of calculations for PAL (November 7, 2003, 68 FR 63021).

II. What action is EPA taking?

EPA is proposing to approve updates and revisions to Wisconsin's air quality SIP. Specifically, EPA is proposing to approve updates to the definition of ''Replacement Unit'' under NR 405.02(12)(b), NR405.02(25k), and NR 408.02(29s), and is approving a revision to a component of the emission calculation used to determine emissions under a PAL under NR 405.18(6)(e) and NR 408.11(6)(e).

III. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Wisconsin Administrative Code provisions NR 405.02(12)(b), 405.18(6)(e), NR 405.02(25k), NR 408.02(29s) and NR 408.11(6)(e), as published in the Wisconsin Register, July, 2008, No. 631 and state effective August 1, 2008. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations.

Dated: November 3, 2020.

Kurt Thiede,

Regional Administrator, Region 5.

[FR Doc. 2020–24776 Filed 11–6–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 5, 25, 97

[IB Docket No. 18–313; Report No. 3158; FRS 17196]

Petitions for Reconsideration of Action in Proceedings

AGENCY: Federal Communications Commission.

ACTION: Petitions for reconsideration.

SUMMARY: Petitions for Reconsideration (Petitions) have been filed in the Commission's proceeding by David Goldman, on behalf of Space Exploration Technologies Corp.; Audrey L. Allison, on behalf of The Boeing Company; Jennifer A. Manner, on behalf of EchoStar Satellite Services, LLC and Hughes Network Services, LLC; Mike Safyan, on behalf of Planet Labs Inc.; Ananda Martin, on behalf of Spire Global, Inc.; Elisabeth Neasmith, on behalf of Telesat Canada; and Julie Zoller, et al., on behalf of Kuiper Systems, Inc.

DATES: Oppositions to the Petitions must be filed on or before November 24, 2020. Replies to an opposition must be filed on or before December 4, 2020.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Merissa Velez, International Bureau, Satellite Division, (202) 418–0751.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3158, released October 6, 2020. Petitions may be accessed online via the Commission's Electronic Comment Filing System at: *http://apps.fcc.gov/ecfs/.* The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801(a)(1)(A), because no rules are being adopted by the Commission.

Subject: Mitigation of Orbital Debris in the New Space Age, FCC 20–54, published 85 FR 52422, August 25, 2020, in IB Docket No. 18–313. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 3.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison.

[FR Doc. 2020–24731 Filed 11–6–20; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 201029–0282]

RIN 0648–XG809

Implementation of Fish and Fish Product Import Provisions of the Marine Mammal Protection Act—Notification of Rejection of Petition and Issuance of Comparability Findings

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

ACTION: Denial of petition and issuance of comparability findings.

SUMMARY: Under the authority of the Marine Mammal Protection Act (MMPA), the NMFS Assistant Administrator for Fisheries (Assistant Administrator) has denied a petition for emergency rulemaking from Sea Shepherd Legal. Additionally, the Assistant Administrator has issued comparability findings for the Government of New Zealand's (GNZ) following fisheries: West Coast North Island multi-species set net fishery, and West Coast North Island multi-species trawl fishery. NMFS bases the comparability findings on documentary evidence submitted by the GNZ and other relevant, readily-available information including the scientific literature.

DATES: These comparability findings are valid for the period of November 6, 2020, through January 1, 2023, unless revoked by the Assistant Administrator in a subsequent action.

FOR FURTHER INFORMATION CONTACT: Nina Young, NMFS F/IASI (Office of International Affairs and Seafood Inspection) at *Nina.Young@noaa.gov* or 301–427–8383.

SUPPLEMENTARY INFORMATION:

Background

The MMPA, 16 U.S.C. 1371 *et seq.,* states that the ''Secretary of the Treasury shall ban the importation of commercial fish or products from fish which have been caught with commercial fishing technology which results in the incidental kill or incidental serious injury of ocean mammals in excess of United States standards.'' For purposes of applying this import restriction, the Secretary of Commerce ''shall insist on reasonable proof from the government of any nation from which fish or fish products will be exported to the United States of the effects on ocean mammals of the commercial fishing technology in use for such fish or fish products exported from such nation to the United States.''

In August 2016, NMFS published a final rule (81 FR 54390; August 15, 2016) implementing the fish and fish product import provisions in section 101(a)(2) of the MMPA. This rule established conditions for evaluating a harvesting nation's regulatory programs to address incidental and intentional mortality and serious injury of marine mammals in fisheries operated by nations that export fish and fish products to the United States.

Under the final rule, fish or fish products may not be imported into the United States from commercial fishing operations that result in the incidental mortality or serious injury of marine mammals in excess of U.S. standards (16 U.S.C. 1371(a)(2)). NMFS published a List of Foreign Fisheries (LOFF) on October 8, 2020 (85 FR 63527), to classify fisheries subject to the import requirements. Effective January 1, 2023, fish and fish products from fisheries identified by the Assistant Administrator in the LOFF may only be imported into the United States if the harvesting nation has applied for and received a comparability finding from NMFS for those fisheries on the LOFF. The rule established the procedures that a harvesting nation must follow, and the conditions it must meet, to receive a comparability finding for a fishery on the LOFF. The final rule established an exemption period, ending January 1, 2023, before imports would be subject to any trade restrictions (see 50 CFR 216.24(h)(2)(ii)).

In that rule's preamble, NMFS stated that it may consider emergency rulemaking to ban imports of fish and fish products from an export or exempt fishery having or likely to have an immediate and significant adverse impact on a marine mammal stock. In addition, pursuant to the MMPA Import Provisions rule, nothing prevents a nation from implementing a bycatch reduction regulatory program and seeking a comparability finding during the five-year exemption period. As discussed below, the Government of New Zealand (GNZ) has requested an early Comparability Finding for several of its fisheries.

The Petition and Request for a Comparability Finding

In February 2019, Sea Shepherd Legal, Sea Shepherd New Zealand Ltd., and Sea Shepherd Conservation Society petitioned NMFS ''for an emergency rulemaking under the [MMPA], asking [the Government] to ban the import of fish caught in gillnet and trawl fisheries in the Māui dolphin's range'' because the Government of New Zealand's (GNZ) 2012 regulations were insufficient to protect the Māui dolphin. On July 10, 2019, NMFS rejected the petition on the basis that the GNZ: (1) Had in place an existing regulatory program to reduce Māui dolphin bycatch; and (2) was proposing to implement in 2019 a regulatory program comparable in effectiveness to the United States which, when fully implemented, would likely further reduce risk and Māui dolphin bycatch below Potential Biological Removal level.[1]

On May 21, 2020, Sea Shepherd New Zealand and Sea Shepherd Conservation Society (collectively, ''Plaintiffs'') initiated a lawsuit in the Court of International Trade (CIT) alleging (1) NMFS' failure to ban imports as required by the MMPA violated the Administrative Procedure Act (5 U.S.C. 706(1)), which prohibits an agency unlawfully withholding or unreasonably delaying action; and (2) that NMFS' denial of its petition was arbitrary and capricious and also violated the Administrative Procedure Act (5 U.S.C. 706(2)(A)). On June 24, 2020, the GNZ announced its final fisheries measures for reducing bycatch of Māui dolphins (effective October 1, 2020) and its final Threat Management Plan (TMP). On July 1, 2020, Plaintiffs moved for a preliminary injunction to ban imports of seafood into the United States from New Zealand's set-net and trawl fisheries.

Before responding to Plaintiffs' motion for a preliminary injunction, NMFS moved for a voluntary remand in order to reconsider the Plaintiffs' petition for emergency rulemaking under the MMPA and requested that the court stay filing deadlines in the case pending decision of the voluntary remand.

On July 15, 2020, the GNZ, acting through the Ministry for Primary Industries, requested that NOAA and NMFS perform a comparability assessment of the TMP and its regulatory program as it relates to Māui's dolphins. The court held oral argument on August 6, 2020. On August 13, 2020, the CIT granted the voluntary remand. The CIT also provided the Plaintiffs the opportunity to supplement their petition within 14 days of the

[1] 16 U.S.C. 1362 The term ''potential biological removal level'' means 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.

court order. The CIT ordered that NMFS file the remand determination, including a determination on GNZ's application for a comparability finding, with the court by October 30, 2020.

On August 27, 2020, NMFS received the supplemental petition, which both maintains the grounds for action outlined in the original petition and includes information that arose after submission of the original petition. The supplemental petition directs attention to the following new information: (1) The receipt of data from the New Zealand government suggesting sightings of Māui dolphins on the East Coast of the North Island; (2) the issuance of the 2019 Draft TMP; (3) the final TMP announced on June 24, 2020; and (4) the 2020 draft LOFF. On September 29, 2020, NMFS published notification of receipt of a supplemental petition to ban imports of all fish and fish products from New Zealand that do not satisfy the MMPA (85 FR 60946).

NMFS is undertaking this action in response to the court-ordered voluntary remand of NMFS' July 10, 2019 decision on the 2019 emergency petition, the 2020 supplemental petition, and the request by the GNZ for a comparability finding during the exemption period.

Māui Dolphin

Māui dolphins (*Cephalorhynchus hectori Māui*) are the northernmost distinct subpopulation of Hector's dolphin species (*Cephalorhynchus hectori*). The scientific community recognized Māui and South Island Hector's dolphins as distinct subspecies in 2002. The Māui dolphin is endemic to the west coast of the North Island of New Zealand and is listed by IUCN as Critically Endangered and as an endangered species under the U.S. Endangered Species Act (16 U.S.C. 1531 *et seq.*). In 1970, scientists estimated that the Māui dolphin population numbered approximately 200 animals. The Māui dolphin population is currently estimated at 63 individuals (95% CI 57–75); with the population declining at the rate of 3–4 percent per year over the period 2001–16. Māui dolphin demographic models now estimate that the population may have stabilized or begun to increase in recent years following a decline in the past 20 to 30 years. Bycatch in gillnets (or set nets) and trawl nets are one of the threats to Māui dolphin.

NMFS Determination on the Petition and the GNZ's Comparability Application

NMFS is rejecting the petition to ban the importation of commercial fish or products from fish harvested in a manner that results in the incidental kill or incidental serious injury of Māui dolphins in excess of U.S. standards, and is issuing a Comparability Finding for the West Coast North Island multi-species set-net and trawl fisheries because the GNZ has implemented a regulatory program governing the bycatch of Māui dolphin that is comparable in effectiveness to U.S. standards.

As a part of the comparability finding process set forth at 50 CFR 216.24(h)(6) and review of the petition, NMFS considered documentary evidence submitted by the GNZ and other relevant, readily-available information including scientific literature and government reports. Specifically, NMFS reviewed the 2019 petition and supplemental petition, supporting documents to those petitions, previous GNZ risk assessments and threat management plans, the 2019 and 2020 TMP and supplemental documents, the 2020 regulatory regime, and the GNZ's comparability finding application.

NMFS is rejecting the petition and has determined that the West Coast North Island multi-species set-net fishery [2] and West Coast North Island multi-species trawl fishery [3] have met the MMPA's requirements to receive comparability findings. In accordance with 50 CFR 216.24(h)(8)(vii), a comparability finding will be terminated or revoked if NMFS determines that the requirements of 50 CFR 216.24(h)(6) are no longer being met. The rationale for the determination announced in this notice is articulated in an analysis of the GNZ application for a comparability finding. The analysis is available from NMFS (see **FOR FURTHER INFORMATION CONTACT**).

The comparability findings for the GNZ's affected fisheries included in this **Federal Register** notice will remain valid through January 1, 2023. All other exempt and export fisheries operating under the control of the GNZ are subject to the exemption period under 50 CFR 216.24(h)(2)(ii). The GNZ is still required to provide all reports and updates to its fisheries on NMFS' LOFF in accordance with 50 CFR 216.24(h) for these fisheries and all other GNZ fisheries on NMFS' LOFF.

Responses to Comments on the Notification of the Petition

NMFS received nine sets of comments on the amended petition from fishing industry groups, environmental non-governmental organizations (NGOs), private citizens, the Marine Mammal Commission (MMC), and Te Ohu Kaimoana.

General Comments

Comment 1: Comments submitted by members of the general public, NGOs, and the MMC supported initiating rulemaking to ban imports of fish and fish products from New Zealand set-net and trawl fisheries operating in Māui dolphin habitat, alleging that the GNZ's regulatory program does not go far enough in protecting Maui dolphins.

Response: NMFS disagrees. The GNZ regulatory program that came into effect on October 1, 2020, is comparable in effectiveness to the U.S. regulatory program. The GNZ prohibits intentional killing and injury of marine mammals and has vessel registration, bycatch reporting, and a monitoring program comparable to the U.S. regulatory program. The GNZ's regulatory program includes calculated bycatch estimates, bycatch limits (potential biological removal level (PBR)) and a population sustainability threshold (PST), and a bycatch mitigation program to reduce and maintain Māui dolphin bycatch below PBR. The program also includes a management review trigger, which is designed to prevent bycatch from exceeding PBR and allows for the immediate imposition of additional bycatch reduction measures in the event that a fishing-related incident does occur. The regulatory program, similar to the U.S. Take Reduction process, includes public participation and periodic review and modification to the regulatory program to ensure that it is meeting its targets and objectives. The regulatory program also includes research projects to improve understanding of Māui dolphins and the threats they face.

Emergency Action

Comment 2: Both NGOs and the MMC assert that emergency rulemaking to ban imports is required because of the small population of Māui dolphins. The MMC

[2] The target species of this multi-species fishery are: Australian salmon (*Arripis trutta*), Bluefin gurnard (*Chelidonichthys kumu*), Common warehou (*Seriolella brama*), Flatfishes nei (*Pleuronectiformes*), Flathead grey mullet (*Mugil cephalus*), Silver seabream (*Pagrus auratus*), Spotted estuary smooth-hound (*Mustelus lenticulatus*), Tope shark (*Galeorhinus galeus*), White trevally (*Pseudocaranx dentex*).

[3] The target species of this multi-species fishery are: Australian salmon (*Arripis trutta*), Blue grenadier (*Macruronus novaezelandiae*), Bluefin gurnard (*Chelidonichthys kumu*), Common warehou (*Seriolella brama*), Jack and horse mackerels nei (*Trachurus spp*), John dory (*Zeus faber*), Silver gemfish (*Rexea solandri*), Silver seabream (*Pagrus auratus*), Snoek (*Thyrsites atun*), Spiny dogfish (*Squalus acanthias*), Spotted estuary smooth-hound (*Mustelus lenticulatus*), Tarakihi/jackass morwong (*Nemadactylus macropterus*), Tarakihi/jackass morwong (*Nemadactylus macropterus*), Tope shark (*Galeorhinus galeus*), Warehou nei (*Seriolella spp*), White trevally (*Pseudocaranx dentex*), Yellowtail amberjack (*Seriola lalandi*).

states that given the small numbers of Māui dolphins remaining, the population's trend over recent decades, the low capacity of the species to withstand further losses, and the ongoing number of deaths of Hector's and Maui dolphins attributed to fisheries bycatch, it is evident that commercial fisheries have and may be continuing to have an impact on the Māui dolphin population.

Response: NMFS disagrees. Māui dolphin demographic models now estimate that the population may have stabilized or begun to increase in recent years following a decline in the past 20 to 30 years. The MMC did note that population estimates of Māui dolphins covering the period since the GNZ established its previous fishery-specific restrictions have varied between 55 and 69 individuals. The MMC also acknowledges that these and earlier estimates suggest that the protection provided by the GNZ's previous (prior to October 1, 2020) regulatory program has slowed the population's decline. Moreover, contrary to claims by the petitioners and the MMC that there are an estimated 14–17 reproductive-aged females remaining, scientists currently place these estimates at 20–35 adult females. According to the GNZ's onboard observer program, there have been no observed bycatch events of Māui or Hector's dolphins in set-net or trawl fisheries operating off the west coast of the North Island. Since 2012, fisheries observers sighted only two free-swimming *Cephalorhynchus* spp. (Māui/Hector's dolphin). Both sightings occurred from trawl vessels, in areas closed to set-nets. There has been one self-reported capture of a *Cephalorhynchus* spp. (Māui/Hector's dolphin) off the west coast of the North Island in January 2012 on a commercial set-net vessel fishing off Cape Egmont, Taranaki. Between 1921 and present there have been five beachcast recovered carcasses of *Cephalorhynchus* spp. dolphins (Māui/Hector's dolphin) off the West Coast North Island where fishing was implicated via necropsy in the cause of death, the last in 2012. In the absence of a declining population or ongoing incidental mortality or serious injury, the petitioners and MMC have failed to demonstrate that the incidental mortality and serious injury of Māui/Hector's dolphin from commercial fisheries is having, or is likely to have, an immediate and significant adverse impact on the subspecies. Emergency rulemaking is not warranted.

Extent of the West Coast Distribution and the East Coast

Comment 3: NGOs claim that sightings in the northern and southern extent of the Māui dolphin distribution along the West Coast of the North Island are evidence of a resident population and necessitate fisheries restrictions in these areas.

Response: The GNZ's regulatory program includes fishery-specific restrictions in the northern and southern ranges and the transitory zone to reduce the bycatch risk in these areas. This action was taken not withstanding that these areas represent a transient and small proportion of the Māui dolphin distribution. These measures concentrate the fishery-specific restrictions in the areas with the greatest overlap between fishing activities and the Māui dolphin population (core area), virtually eliminating the bycatch risk from set-nets and significantly reducing the trawl bycatch risk for Māui dolphins in this area. The GNZ's regulatory measures, in all likelihood, will reduce bycatch below PBR, making them comparable in effectiveness to U.S. standards.

Comment 4: NGOs claim that a resident population of Māui dolphins exists off the East Coast of the North Island, based on sightings. The NGOs assert that the GNZ must extend protection to this area including restrictions on set-nets and trawl gear.

Response: The GNZ, the New Zealand fishing industry, and Te Ohu Kaimoana (a New Zealand charitable trust for Maori fishing rights) assert that the petitioners have misrepresented the GNZ sighting data (*e.g.,* claiming all sightings as Māui dolphins) and that no genetically-tested *Cephalorhynchus hectori sp.* dolphin found on the East Coast of the North Island has been identified as a Māui dolphin. The map provided by the petitioners in the supplemental petition is a distortion of the sighting information available through the GNZ's Department of Conservation. The sighting information does not denote any dolphins on the East Coast as being Māui dolphins—to the contrary, all are denoted as being Hector's dolphins. To date, there is no evidence of a resident dolphin population of either subspecies in any North Island location outside of the recognized core range of Māui dolphins (*i.e.,* there have been no verified sightings of breeding aggregations or newborn calves, and the sightings do not conform to any predictable seasonal pattern). The literature, the absence of far-ranging migratory movements by Māui dolphins, and the sighting data clearly show the absence of confirmed sightings of Māui dolphin on the east coast of the North Island and do not support the existence of either a resident or ''transient'' population of Māui dolphins.

Risk Assessment and Habitat Models

Comment 5: NGOs claim that the GNZ risk assessment model underestimates fisheries mortality. Likewise, they claim that the habitat model is flawed by restricting the overlap of the Māui dolphin distribution and overestimating the benefits of the protective measures. The MMC states that the model uses biased and high abundance estimates, a high reproductive rate, and an assumed figure for calf survival. The MMC suggests that NMFS use a precautionary approach when considering the GNZ's comparability finding application and the data used to support its request.

Response: As alleged by the commenters, the GNZ's risk assessment methodology does not use the low overall observer coverage and the likely under-reporting of captures by fishers. Rather, the model pooled all available observer data for set-netting including that for the South Island coastal fleet where observer coverage is higher and the likelihood of a dolphin encountering a net was higher and estimated the likelihood of a Māui dolphin being captured in a set-net. As the model estimates probability of capture or death per dolphin, per fishing event, it is insensitive to actual population size and can be used to evaluate risk in locations where population size is unknown or hypothetical.

NMFS notes that while some scientists may disagree about the assumptions that serve as the basis for the risk assessment models that underpin the GNZ bycatch estimates, NMFS finds that the approach taken in the risk assessment is reasonable. The MMPA Import Provisions do not mandate that the United States (specifically NMFS) arbitrate such scientific debates or disagreements. The MMPA Import Provisions do not require that a nation's approach be identical to the U.S. regulatory program or standards, just comparable in effectiveness to those standards. The MMPA Import Provisions also do not require an evaluation of the implementation of historic bycatch reduction or regulatory programs when making a comparability finding. The standard of the MMPA Import Provisions is that a nation currently has a regulatory program comparable in effectiveness to the U.S. regulatory program. Based on NMFS' analysis of all readily available data, the petition, and

the reasonable proof supplied by the GNZ, the GNZ regulatory program that came into effect on October 1, 2020, is comparable in effectiveness to the U.S. regulatory program.

Bycatch Limits

Comment 6: The NGOs claim that the GNZ's use of the PST instead of PBR increases the level of acceptable bycatch. They also assert that PBR should be calculated using a net productivity rate of 0.018, resulting in a PBR of one dolphin every 20.6 years.

Response: The NGOs and petitioners are in error on two points. First, the GNZ PST as calculated in the final TMP (PST = 0.14) is a comparable scientific metric to PBR (PBR = 0.11). Regardless of the differences in the PBR/PST calculations, the GNZ, for the purpose of its comparability finding application, is using and has calculated a PBR for Māui dolphins of 0.11 as its biological threshold or bycatch limit. Therefore, the standard used by the GNZ is PBR and is comparable to U.S. standards, and NMFS finds the underlying data inputs appropriate. Second, the NGOs and petitioners' calculation does not conform to the U.S. ''Guidelines for Preparing Stock Assessment Reports Pursuant to the 1994 Amendments to the MMPA,'' which states: Substitution of other values of the maximum net productivity rate (R_{max}) should be made with caution, and only when reliable stock-specific information is available on R_{max} (*e.g.,* estimates published in peer-reviewed articles or accepted by review groups such as the MMPA Scientific Review Groups or the Scientific Committee of the International Whaling Commission). The NGOs' and the petitioners' calculation relies on dated estimates for R_{max}, is inconsistent with the known age at first reproduction of Māui dolphins, underestimates maximum age for this species, and is contrary to more recent estimates of R_{max} in the literature. Moreover, the Māui dolphin demographic models now estimate that the population may have stabilized or begun to increase in recent years following a decline in the past 20 to 30 years. Therefore, NMFS finds the NGO's and petitioners' PBR estimate is not comparable to U.S. standards.

Monitoring

Comment 7: The NGOs claim that the GNZ's requirement for electronic monitoring of set-net and trawl fisheries is an inadequate measure. They base this claim on supposition that too few fishing vessels have been outfitted with camera systems and that such systems will not be fully operational until 2023. The MMC claims that the GNZ, under its new regulatory program, does not increase observer coverage in the set-net fishery and that camera monitoring is only on the South Island.

Response: Both the NGOs and the MMC are incorrect. Since November 1, 2019, on-board cameras are required on any set-net or trawl vessel (≥8 m and ≤29 m in registered length). The area where onboard cameras are required covers the coastal area of the Māui dolphin habitat zone, except for a small portion in the far north estimated to have a low density of dolphins, and extends into the northern portion of the southern transition zone. According to the GNZ, the requirement applies to 28 vessels, of which 20 have opted into the on-board camera requirement; the other eight vessels subject to the regulatory requirement are currently not operating in the defined area. Any authorized vessel without on-board cameras must carry an observer. Thus, fishing vessels currently operating in the core Māui dolphin habitat zone have 100 percent coverage of electronic monitoring. The GNZ bycatch monitoring program is comparable in effectiveness to U.S. standards. Finally, according to the GNZ, the 2023 date refers to broader implementation of on-board cameras including on the South Island and not the implementation of this program to the West Coast of the North Island.

Traceability

Comment 8: NGOs claim New Zealand's fishery traceability system is not structured to trace fishery catches and/or marine mammal bycatch incidents back to specific fisheries management areas. They assert that NMFS should not use this deficiency as an excuse to not impose the required fishery product import bans under the MMPA. The NGOs also claim that New Zealand's marine mammal bycatch traceability system is not consistent with the standards imposed on fisheries in the United States.

Response: As discussed in the response to comment 7, the GNZ's monitoring program, including its observer programs and on-board cameras, is comparable in effectiveness to U.S. standards requiring monitoring. The GNZ's monitoring program is sufficient to detect and estimate bycatch. The MMPA Import Provisions do not require, as a condition for a comparability finding, a seafood traceability system.

Dated: October 26, 2020.

Paul N. Doremus,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 2020–24416 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 201102–0286; RTID 0648–XP014]

Pacific Island Pelagic Fisheries; 2021 U.S. Territorial Longline Bigeye Tuna Catch Limits

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

ACTION: Proposed specifications; request for comments.

SUMMARY: NMFS proposes a 2021 limit of 2,000 metric tons (t) of longline-caught bigeye tuna for each U.S. Pacific territory (American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands (CNMI) (the territories)). NMFS would allow each territory to allocate up to 1,500 t in 2021 to U.S. longline fishing vessels through specified fishing agreements that meet established criteria. However, the overall allocation limit among all territories may not exceed 3,000 t. As an accountability measure, NMFS would monitor, attribute, and restrict (if necessary) catches of longline-caught bigeye tuna, including catches made under a specified fishing agreement. The proposed catch limits and accountability measures would support the long-term sustainability of fishery resources of the U.S. Pacific Islands.

DATES: NMFS must receive comments by November 24, 2020.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2020–0010, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0010,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Send written comments to Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands

Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

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

Pursuant to the National Environmental Policy Act, the Western Pacific Fishery Management Council (Council) and NMFS prepared a 2019 environmental assessment (EA), a 2020 supplemental environmental assessment (SEA), and a 2020 supplemental information report (SIR) that support this proposed action. The EA, SEA, and SIR are available at *www.regulations.gov,* or from the Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, *www.wpcouncil.org.*

FOR FURTHER INFORMATION CONTACT: Lynn Rassel, NMFS PIRO Sustainable Fisheries, 808–725–5184.

SUPPLEMENTARY INFORMATION: NMFS proposes to specify a 2021 catch limit of 2,000 t of longline-caught bigeye tuna for each U.S. Pacific territory. NMFS would also authorize each U.S. Pacific territory to allocate up to 1,500 t of its 2,000 t bigeye tuna limit, not to exceed a 3,000 t total annual allocation limit among all the territories, to U.S. longline fishing vessels that are permitted to fish under the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific (FEP). Those vessels must be identified in a specified fishing agreement with the applicable territory. The Council recommended these specifications.

The proposed catch limits and accountability measures are identical to those that NMFS has specified for U.S. Pacific territories in each year since 2014. The proposed individual territorial allocation limit of 1,500 t is identical to what NMFS specified for 2020. The overall allocation limit among all of the territories may not exceed 3,000 t for the year, which is consistent with previous years. NMFS has determined that the existing EA and SEA adequately address the potential impacts on the human environment by the proposed action, and that no additional analyses are required.

NMFS will monitor catches of longline-caught bigeye tuna by the longline fisheries of each U.S Pacific territory, including catches made by U.S. longline vessels operating under specified fishing agreements. The criteria that a specified fishing agreement must meet, and the process for attributing longline-caught bigeye tuna, will follow the procedures in 50 CFR 665.819. When NMFS projects that a territorial catch or allocation limit will be reached, NMFS would, as an accountability measure, prohibit the catch and retention of longline-caught bigeye tuna by vessels in the applicable territory (if the territorial catch limit is projected to be reached), and/or vessels in a specified fishing agreement (if the allocation limit is projected to be reached).

NMFS will consider public comments on the proposed action and will announce the final specifications in the **Federal Register**. NMFS also invites public comments that address the impact of this proposed action on cultural fishing in American Samoa.

NMFS must receive any comments on this proposed action by the date provided in the **DATES** heading. NMFS may not consider any comments not postmarked or otherwise transmitted by that date. Regardless of the final specifications, all other existing management measures will continue to apply in the longline fishery.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator has determined that this proposed specification is consistent with the FEP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

Certification of Finding of No Significant Impact on Substantial Number of Small Entities

The Chief Counsel for Regulation for the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that these proposed specifications, if adopted, would not have a significant economic impact on a substantial number of small entities.

The proposed action would specify a 2021 limit of 2,000 t of longline-caught bigeye tuna for each U.S. Pacific territory. NMFS would also allow each territory to allocate up to 1,500 t of its 2,000 t limit, not to exceed an overall annual allocation limit of 3,000 mt, to U.S. longline fishing vessels in a specified fishing agreement that meets established criteria set forth in 50 CFR 665.819. As an accountability measure, NMFS would monitor, attribute, and restrict (if necessary) catches of longline-caught bigeye tuna by vessels in the applicable U.S. territory (if the territorial catch limit is projected to be reached), or by vessels operating under the applicable specified fishing agreement (if the allocation limit is projected to be reached). Payments under the specified fishing agreements support fisheries development in the U.S. Pacific territories and the long-term sustainability of fishery resources of the U.S. Pacific Islands.

This proposed action would directly apply to longline vessels federally permitted under the FEP, specifically Hawaii, American Samoa, and Western Pacific longline permit holders. Preliminary data presented to the 183rd meeting of the Western Pacific Fishery Management Council on September 17, 2020, shows that from January 1, 2020, to June 20, 2020, 164 vessels had Hawaii longline permits, with 145 of these vessels actively participating in the fishery and 60 had American Samoa longline permits, with 10 of these vessels actively participating in the fishery. There are no active Western Pacific general longline permitted vessels.

Based on dealer data collected by the State of Hawaii and the Pacific Fisheries Information Network, Hawaii longline vessels landed approximately 26.7 million lb (12,111 t) of pelagic fish valued at $94.7 million in 2019. With 146 vessels making either a deep- or shallow-set trip in 2019, the ex-vessel value of pelagic fish caught by Hawaii-based longline fisheries averaged almost $649,000 per vessel. In 2019, American Samoa-based longline vessels landed approximately 3.0 million lb (1,361 t) of pelagic fish valued at $3.9 million, with albacore making up the largest proportion of pelagic longline commercial landings. With 17 active longline vessels in 2019, the ex-vessel value of pelagic fish caught by the American Samoa fishery averaged almost $230,000 per vessel.

Dealer data are not yet available for 2020. However, preliminary information for 2020 indicates that the longline fisheries are experiencing some drop in prices, landings, revenue and other fishery performance measures, due to the effects of travel restrictions and reduced tourism on market demand for locally caught seafood. In Hawaii, drastic declines in tourism have led to

a significant reduction in demand for associated goods and services including locally caught seafood. These, in turn, affected fishery landings, fish prices, and revenues. Average revenues, landings and prices from March through July dropped 45 percent, 34 percent, and 15 percent respectively compared to averages for 2015–2019 (NMFS Pacific Islands Fisheries Science Center, unpublished data). In American Samoa, 2020 longline fishing activity is also likely to have been similarly adversely affected, compounded by the imposition of incoming travel restrictions, which has affected the recruitment of fishing crew. However, travel and other restrictions are likely to ease, which would help boost market demand for locally caught seafood, market prices, and fishing effort.

NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. Based on available information, NMFS has determined that all vessels permitted federally under the FEP are small entities, *i.e.,* they are engaged in the business of fish harvesting (NAICS 114111), are independently owned or operated, are not dominant in their field of operation, and have annual gross receipts not in excess of $11 million. Even though this proposed action would apply to a substantial number of vessels, the implementation of this action would not result in significant adverse economic impact to individual vessels. The proposed action would potentially benefit the Hawaii longline fishermen by allowing them to fish under specified fishing agreements with a territory, which could extend fishing effort for bigeye tuna in the western Pacific and provide more bigeye tuna for markets in Hawaii and elsewhere.

In accordance with Federal regulations at 50 CFR part 300, subpart O, vessels that possess both an American Samoa and Hawaii longline permit are not subject to the U.S bigeye tuna limit. Therefore, these vessels may retain bigeye tuna and land fish in Hawaii after the date NMFS projects the fishery would reach that limit. Further, catches of bigeye tuna made by such vessels are attributed to American Samoa, provided the fish was not caught in the U.S. exclusive economic zone around Hawaii.

The 2021 U.S. bigeye tuna catch limit is 3,554 t, which is the same limit in place for 2020. With regard to the 2020 fishing year, NMFS received a specified fishing agreement between American Samoa and the Hawaii Longline Association (HLA), which included a specification of 1,000 t of bigeye tuna. NMFS began allocating catches to American Samoa on September 6, 2020, prior to the U.S. fishery reaching the bigeye tuna catch limit. Based on logbooks submitted by longline vessels, the American Samoa allocation would likely be reached sometime in November 2020, at which time HLA would likely enter into an agreement with the CNMI. These combined measures, including the remaining available U.S. limit and one or more specified fishing agreements, should enable the U.S fishery to fish through the end of 2020.

As with 2020 and prior years, this proposed action would allow Hawaii-based longline vessels to enter into one or more fishing agreements with participating U.S. Pacific territories. This would enhance the ability of these vessels to extend fishing effort in the western and central Pacific Ocean after reaching the 2021 U.S. limit and provide more bigeye tuna for markets in Hawaii. Providing opportunity to land bigeye tuna in Hawaii in the last quarter of the year when market demand is generally high will result in positive economic benefits for fishery participants and net benefits to the nation. Allowing participating territories to enter into specified fishing agreements under this action is consistent with Western and Central Pacific Fishery Commission (WCPFC) conservation and management objectives for bigeye tuna in Conservation and Management Measure 2018–01, and benefits the territories by providing funds for territorial fisheries development projects. Establishing a 2,000 t longline limit for bigeye tuna, where territories are not subject to WCPFC longline limits, is not expected to adversely affect vessels based in the territories.

Historical catches of bigeye tuna by the American Samoa longline fleet have been less than 2,000 t, including the catch of vessels based in American Samoa, catch by dual permitted vessels that land their catch in Hawaii, and catch attributed to American Samoa from U.S. vessels under specified fishing agreements. No longline fishing has occurred since 2011 in Guam or the CNMI.

Under the proposed action, longline fisheries managed under the FEP are not expected to expand substantially or change the manner in which they are currently conducted (*i.e.,* area fished, number of vessels and trips, number and depth of hooks, or deployment techniques) due to existing operational constraints in the fleet, the limited entry permit programs, and protected species mitigation requirements. The proposed action does not duplicate, overlap, or conflict with other Federal rules and is not expected to have significant impact on small organizations or government jurisdictions. Furthermore, there would be little, if any, disproportionate adverse economic impacts from the proposed action based on gear type, or relative vessel size. The proposed action also will not place a substantial number of small entities, or any segment of small entities, at a significant competitive disadvantage to large entities.

For the reasons above, NMFS does not expect the proposed action to have a significant economic impact on a substantial number of small entities. As such, an initial regulatory flexibility analysis is not required and none has been prepared.

This action is exempt from review under Executive Order 12866.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

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

Dated: November 3, 2020.

Samuel D. Rauch III,

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

[FR Doc. 2020–24750 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 85, No. 217

Monday, November 9, 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

November 3, 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 December 9, 2020 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.

Animal and Plant Health Inspection Service

Title: U.S. Origin Health Certificate.

OMB Control Number: 0579–0020.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The AHPA is contained in Title X, Subtitle E, Sections 10401–18 of Public Law 107–171, May 13, 2002, the Farm Security and Rural Investment Act of 2002. As part of its mission to facilitate the export of U.S. animals and products, the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), maintains information regarding the import health requirements of other countries for animals and animal products exported from the United States. Most countries require a certification that the animals are disease free.

To ensure a favorable balance of trade and compliance with export health requirements, APHIS uses information collection activities such as U.S. Origin Health Certificates; U.S. Interstate and International Certificates of Health Examinations for Small Animals; U.S. Origin Health Certificates for the Export of Horses from the United States to Canada; Health Certificates for the Export of Live Finfish, Mollusks, and Crustaceans (and their Gametes); Undue Hardship Explanations-Animals; Applications for Approval of Inspection Facility-Environmental Certification; Annual Inspections of Inspection Facilities; Opportunities to Present Views Concerning Withdrawal of Facility Approval; Certifications to Carry Livestock; Inspections of Vessel Prior to Voyage; Notarized Statements; Aircraft Cleaning and Disinfection; Country-Specific Health Care; and Travel Time.

Need and Use of the Information: The collection of this information prevents unhealthy animals from being exported from the United States. The information collected is used to: (1) Establish that the animals are moved in compliance with USDA regulations, (2) verify that the animals destined for export are listed on the health certificate by means of an official identification, (3) verify to the consignor and consignee that the animals are healthy, (4) prevent unhealthy animals from being exported and (5) satisfy the import requirements of receiving countries. If these certifications were not provided, other countries would not accept animals from the United States.

Description of Respondents: Farms; Business or other for profit.

Number of Respondents: 4,072.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 424,316.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–24761 Filed 11–6–20; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Farm Service Agency, Department of Agriculture.

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the Department of Agriculture (USDA), Farm Service Agency (FSA) has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to OMB for approval under the Paperwork Reduction Act (PRA).

DATES: Comments must be submitted by December 9, 2020.

ADDRESSES: 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.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** of September 4, 2020 (85 FR 55252).

Farm Service Agency 0560–0286

Type of Review: Extension.

Affected Public: Individuals and Households; Businesses; Organizations; and State and Local Government.

Average Expected Annual Number of Activities: 8.

Respondents: 210,500.

Annual responses: 210,500.

Frequency of Response: Once per request.

Average Minutes per Response: 1.

Burden Hours: 37,333.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–24827 Filed 11–6–20; 8:45 am]

BILLING CODE 3410–05–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Georgia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Georgia Advisory Committee (Committee) will hold a meeting via web conference on Tuesday, December 8, 2020, at 10:00 a.m. Eastern Time for the purpose of discussing civil rights concerns in the state.

DATES: The meeting will be held on Tuesday, December 8, 2020 at 10:00 a.m. Eastern Time.

Public Call Information:

Join online: *https://civilrights.webex.com/civilrights/j.php?MTID=mfb8288b9cfabab5cae8645022d8c100e.*

Join by phone:

- 800–360–9505 USA Toll Free
- Access code: 199 251 7253

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or 202–618–4158.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the above listed toll-free number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Melissa Wojnaroski at *mwojnaroski@usccr.gov* in the Regional Program Unit Office/Advisory Committee Management Unit. Persons who desire additional information may contact the Regional Programs Unit Office at 202–618–4158.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkxAAA* under the Commission on Civil Rights, Georgia Advisory Committee link. Persons interested in the work of this Committee are also directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit office at the above email or phone number.

Agenda

Welcome and Roll Call

Discussion: Civil Rights in Georgia (Civil Asset Forfeiture)

Public Comment

Adjournment

Dated: November 4, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–24850 Filed 11–6–20; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Nebraska Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Nebraska Advisory Committee (Committee) will hold a meeting on Thursday, November 5, 2020 at 12:00 p.m. Central time. The Committee will discuss civil rights concerns in the state.

DATES: The meeting will take place on Thursday, November 5, 2020 at 12:00 p.m. Central time.

Public Call Information:

Join online: *https://civilrights.webex.com/civilrights/j.php?MTID=m3cd13ddb005c3be880ddf1aa06968166*

Join by phone:

- 800–360–9505 USA Toll Free
- Access code: 199 936 4884

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or (202) 618–4158

SUPPLEMENTARY INFORMATION: Members of the public can listen to these discussions. Committee meetings are available to the public through the above call in number. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Theconference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individual who is deaf, deafblind and hard of 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 also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324, or emailed to Corrine Sanders at *csanders@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Nebraska Advisory Committee link. 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

Welcome and Roll Call
Civil Rights in Nebraska
Future Plans and Actions
Public Comment
Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given fewer than 15 calendar days prior to the meeting because of the exceptional circumstances of the Committee's upcoming tesitmony.

Dated: November 4, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–24851 Filed 11–6–20; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Survey of Residential Building or Zoning Permit Systems

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, 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 on the proposed extension of the Survey of Residential Building or Zoning Permit Systems, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 8, 2021.

ADDRESSES: Interested persons are invited to submit written comments by email to *Thomas.J.Smith@census.gov.* Please reference Survey of Residential Building or Zoning Permit Systems in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2020–0028, to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to William Abriatis, U.S. Census Bureau, Economic Indicators Division, (301) 763–3686, or *william.m.abriatis@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau plans to request a three-year extension of a currently approved collection of the Form C–411. The Census Bureau produces statistics used to monitor activity in the large and dynamic construction industry. These statistics help state and local governments and the Federal government, as well as private industry, to analyze this important sector of the economy.

The Census Bureau uses the Form C–411 or questions from the form to obtain information needed to update the universe of permit-issuing places from state and local building permit and zoning officials. Questions on the form pertain to the legal requirements for issuing building or zoning permits in

the local jurisdictions. Information is obtained on such items as geographic coverage and types of construction for which permits are issued.

The universe of permit-issuing places is the sampling frame for the Building Permits Survey (BPS) and the Survey of Construction (SOC). These two sample surveys provide widely used measures of construction activity, including the monthly Principal Federal Economic Indicators Housing Units Authorized by Building Permits and Housing Starts.

II. Method of Collection

One of three variants of the Form C–411 is sent to a jurisdiction when the Census Bureau has reason to believe that a new permit system has been established or an existing one has changed. This is based on information the Census Bureau obtains from a variety of sources including survey respondents, regional planning councils, and data from the Census Bureau's Geography Division on newly incorporated jurisdictions. While the C–411 is currently a mailed paper form, the Census Bureau is considering adding this collection to the standard online collection instrument (Centurion) in the future.

There are three versions of the form:

- C–411(V) for verification of coverage for jurisdictions with existing permit systems
- C–411(M) for municipalities where a new permit system may have been established
- C–411(C) for counties where new permit systems may have been established.

Forms are mailed every five years to approximately 3,500 jurisdictions that the Census Bureau has reason to believe have new or changed permit-issuing places. The Census Bureau may follow up with individual jurisdictions between mailings via email or phone as necessary to maintain the permit issuing universe. The Census Bureau follows up with approximately 150 jurisdictions annually between mailouts. The next 5-year mailout is scheduled for 2022.

III. Data

OMB Control Number: 0607–0350.

Form Number(s): C–411(V), C–411(M), and C–411(C).

Type of Review: Regular submission, Request for an Extension, without Change, of a Currently Approved Collection.

Affected Public: State or local governments.

Estimated Number of Respondents: 820 responses (averaged from 5 years of responses).

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 205 hours.

Estimated Total Annual Cost to Public: $0. (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Sections 131 and 182.

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. 2020–24765 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–151–2020]

Approval of Expansion of Subzone 65A; Eastern Shipbuilding Group, Inc.; Panama City and Port St. Joe, Florida

On August 27, 2020, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Panama City Port Authority, grantee of FTZ 65, requesting expanded subzone status subject to the existing activation limit of FTZ 65, on behalf of Eastern Shipbuilding Group, Inc., in Panama City and Port St. Joe, Florida.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (85 FR 54345–54346, September 1, 2020). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to expand Subzone 65A was approved on November 3, 2020, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 65's 2,000-acre activation limit.

Dated: November 3, 2020.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2020–24801 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–813]

Citric Acid and Certain Citrate Salts From Belgium: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that S.A. Citrique Belge N.V. (Citrique Belge), the sole respondent subject to this antidumping duty (AD) administrative review, did not make sales of subject merchandise at less than normal value during the period of review (POR) January 8, 2018 through June 30, 2019. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Stephanie Berger, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2483.

SUPPLEMENTARY INFORMATION:

Background

On September 9, 2019, Commerce published a notice initiating an AD administrative review of citric acid and certain citrate salts (citric acid) from Belgium covering Citrique Belge for the POR.[1] On March 13, 2020, Commerce extended the deadline for issuing the preliminary results of this review.[2] On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days.[3] On July 21, 2020 Commerce tolled all deadlines in administrative reviews by 60 days, thereby extending the deadline for these preliminary results until November 17, 2020.[4] For a complete description of the events that followed, *see* the Preliminary Decision Memorandum.[5] A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 47242 (September 9, 2019).

[2] *See* Memorandum, ''Citric Acid and Certain Citrate Salts from Belgium: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated March 13, 2020.

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[4] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2018–2019 Antidumping Duty Administrative Review: Citric Acid and Certain Citrate Salts from Belgium,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Scope of the Order

The merchandise covered by this order includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. The scope also includes blends of citric acid, sodium citrate, and potassium citrate; as well as blends with other ingredients, such as sugar, where the unblended form(s) of citric acid, sodium citrate, and potassium citrate constitute 40 percent or more, by weight, of the blend.

The scope also includes all forms of crude calcium citrate, including dicalcium citrate monohydrate, and tricalcium citrate tetrahydrate, which are intermediate products in the production of citric acid, sodium citrate, and potassium citrate.

The scope includes the hydrous and anhydrous forms of citric acid, the dihydrate and anhydrous forms of sodium citrate, otherwise known as citric acid sodium salt, and the monohydrate and monopotassium forms of potassium citrate. Sodium citrate also includes both trisodium citrate and monosodium citrate which are also known as citric acid trisodium salt and citric acid monosodium salt, respectively.

The scope does not include calcium citrate that satisfies the standards set forth in the United States Pharmacopeia and has been mixed with a functional excipient, such as dextrose or starch, where the excipient constitutes at least 2 percent, by weight, of the product.

Citric acid and sodium citrate are classifiable under 2918.14.0000 and 2918.15.1000 of the Harmonized Tariff Schedule of the United States (HTSUS), respectively. Potassium citrate and crude calcium citrate are classifiable under 2918.15.5000 and, if included in a mixture or blend, 3824.99.9295 of the HTSUS. Blends that include citric acid, sodium citrate, and potassium citrate are classifiable under 3824.99.9295 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Export price has been calculated in accordance with section 772 of the Act. Normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Results of the Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the period January 8, 2018 through June 30, 2019:

Exporter/producer	Estimated weighted-average dumping margin (percent)
S.A. Citrique Belge N.V	0.00

Disclosure and Public Comment

Commerce intends to disclose the calculations used in its analysis to interested parties in this review within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties are invited to comment on the preliminary results of this review. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[6] Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue, (2) a brief summary of the argument, and (3) a table of authorities.[7] Case and rebuttal briefs should be filed using ACCESS.[8] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[9]

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register**. If a hearing is requested, Commerce will notify interested parties of the hearing date and time. Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of hearing participants; and (3) a list of the issues to be discussed in the hearing. Issues raised in the hearing will

[6] *See* 19 CFR 351.309(d).

[7] *See* 19 CFR 351.309(c)(2) and (d)(2).

[8] *See* 19 CFR 351.

[9] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

We intend to issue the final results of this administrative review, including the results of our analysis of issues raised by the parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**, unless otherwise extended.[10]

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[11] If Citrique Belge's calculated weighted-average dumping margin is above *de minimis* (*i.e.,* greater than or equal to 0.5 percent) in the final results of this review, we will calculate importer-specific assessment *ad valorem* rates based on the ratio of the total amount of antidumping duties calculated for the importer's examined sales and the total entered value of the sales in accordance with 19 CFR 351.212(b)(1). If Citrique Belge's weighted-average dumping margin continues to be zero or *de minimis,* or the importer-specific assessment rate is zero or *de minimis* in the final results of review, we intend to instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[12] The final results of this review will be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review where applicable.

In accordance with our ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Citrique Belge for which Citrique Belge did not know that the merchandise it sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[13] We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of citric acid from Belgium entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Citrique Belge will be the rate established in the final results of this administrative review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the producer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value investigation but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 19.30 percent, the all-others rate established in the less-than-fair-value investigation.[14] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: November 3, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Methodology
V. Date of Sale
VI. Product Comparisons
VII. Export Price and Constructed Export Price
VIII. Normal Value
IX. Currency Conversion
X. Recommendation

[FR Doc. 2020–24829 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–900]

Diamond Sawblades and Parts Thereof From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that diamond sawblades and parts thereof from the People's Republic of China (China) were not sold at less than normal value during the period of review (POR) November 1, 2017 through October 31, 2018.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Bryan Hansen, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3683.

SUPPLEMENTARY INFORMATION:

Background

On January 16, 2020, Commerce published in the **Federal Register** the preliminary results of the 2017–2018 administrative review of the antidumping duty order on diamond sawblades and parts thereof from China.[1] We invited interested parties to

[10] *See* section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

[11] *See* 19 CFR 351.212(b)(1).

[12] *See* 19 CFR 351.106(c)(2).

[13] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[14] *See Citric Acid and Certain Citrate Salts from Belgium, Colombia and Thailand: Antidumping Duty Orders,* 83 FR 35214 (July 25, 2018).

[1] *See Diamond Sawblades and Parts Thereof from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2017–2018,* 85 FR 2705 (January 16, 2020) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

comment on the *Preliminary Results* and we received a case brief from the petitioner, the Diamond Sawblades Manufacturers' Coalition,[2] and a rebuttal brief from Chengdu Huifeng New Material Technology Co., Ltd., the Jiangsu Fengtai Single Entity, and Wuhan Wanbang Laser Diamond Tools Co., Ltd.[3]

On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days, thereby tolling the deadline for the final results of review.[4] On June 15, 2020, Commerce extended the deadline for the final results of review, thereby extending the deadline for the final results of review.[5] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days, thereby tolling the deadline for the final results of review until November 2, 2020.[6]

Scope of the Order

The merchandise subject to the antidumping duty order is diamond sawblades and parts thereof, which is typically imported under heading 8202.39.00.00 of the Harmonized Tariff Schedule of the United States (HTSUS). When packaged together as a set for retail sale with an item that is separately classified under headings 8202 to 8205 of the HTSUS, diamond sawblades or parts thereof may be imported under heading 8206.00.00.00 of the HTSUS. On October 11, 2011, Commerce included the 6804.21.00.00 HTSUS classification number to the customs case reference file, pursuant to a request by U.S. Customs and Border Protection (CBP). Pursuant to requests by CBP, Commerce included to the customs case reference file the following HTSUS classification numbers: 8202.39.0040 and 8202.39.0070 on January 22, 2015, and 6804.21.0010 and 6804.21.0080 on January 26, 2015.

While the HTSUS numbers are provided for convenience and customs purposes, the written description is dispositive. A full description of the scope of the order is contained in the Issues and Decision Memorandum.[7]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in this review are addressed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, follows 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 *http://enforcement.trade.gov/frn/.*

Final Determination of No Shipments

We preliminarily found that Danyang Weiwang Tools Manufacturing Co., Ltd., Danyang Hantronic Import & Export Co., Ltd., and Weihai Xiangguang Mechanical Industrial Co., Ltd., which have been eligible for separate rates in previous segments of the proceeding and are subject to this review, did not have any shipments of subject merchandise during the POR.[8] On February 21, 2020, we received confirmation that U.S. Customs and Border Protection (CBP) found no shipments by any of these companies during the POR.[9] No party commented on the *Preliminary Results* regarding the no shipments decision. Therefore, for these final results, we continue to find that these companies did not have any shipments of subject merchandise during the POR and will issue appropriate instructions to CBP based on these final results.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* and for the reasons explained in the Issues and Decision Memorandum, we made revisions to our preliminary calculations of the weighted-average dumping margin for the single mandatory respondent, Chengdu Huifeng, but the revisions did not result in a change to the weighted-average margin for Chengdu Huifeng and the margin assigned to the separate rate respondents.

Separate Rate for Non-Selected Companies

In the *Preliminary Results,* we found that evidence provided by Bosun Tools Co., Ltd., Chengdu Huifeng New Material Technology Co., Ltd., the Jiangsu Fengtai Single Entity, Wuhan Wanbang Laser Diamond Tools Co., Ltd., Xiamen ZL Diamond Technology Co., Ltd., and Zhejiang Wanli Tools Group Co., Ltd., supported finding an absence of both *de jure* and *de facto* government control, and, therefore, we preliminarily granted a separate rate to each of these companies/company groups.[10] We received no comments since the issuance of the *Preliminary Results* regarding our determination that these six companies/company groups are eligible for a separate rate. As in the *Preliminary Results,* Commerce calculated a rate for the mandatory respondent Chengdu Huifeng that is zero, *de minimis,* or based entirely on facts available. Therefore, in accordance with section 735(c)(5)(A) of the Act and its prior practice, Commerce assigned Chengdu Huifeng's calculated rate (*i.e.,* 0.00 percent) as the separate rate for the non-examined separate rate exporters for these final results.[11]

China-Wide Entity

As stated in the *Preliminary Results,* because no party requested a review of the China-wide entity in this review, the entity is not under review and the entity's rate is not subject to change (*i.e.,* 82.05 percent).[12] Aside from the no-

[2] *See* Petitioner's Letter, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: DSMC's Case Brief,'' dated February 18, 2020.

[3] *See* Chengdu Huifeng Diamond Tools Co., Ltd., the Jiangsu Fengtai Single Entity, and Wuhan Wanbang Laser Diamond Tools Co., Ltd.'s Letter, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Submission of Chengdu Huifeng's Administrative Rebuttal Brief,'' dated March 2, 2020. The Jiangsu Fengtai Single Entity is comprised of Jiangsu Fengtai Diamond Tool Manufacturer Co., Ltd., Jiangsu Fengtai Diamond Tools Co., Ltd., and Jiangsu Fengtai Sawing Industry Co., Ltd.

[4] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[5] *See* Memorandum, ''Diamond Sawblades and Parts Thereof from the People's Republic of China; 2017–2018: Extension of Time Limit for Final Results of Antidumping Duty Administrative Review,'' dated June 15, 2020.

[6] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020. Because the new deadline falls on November 1, 2020, which a Sunday, the deadline has been moved to the next business day, in accordance with our regulations. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005) (Next Business Day Rule).

[7] *See* Memorandum, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review; 2017–2018,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[8] *See Preliminary Results,* 85 FR at 2706.

[9] *See* Memorandum, ''Diamond sawblades and parts thereof from China (A–570–900),'' dated February 21, 2020.

[10] *See* the ''Separate Rates'' section of the Preliminary Decision Memorandum.

[11] For more details on our methodology in selecting a rate for a non-examined separate rate exporter, *see* the ''Separate Rates'' section of the Issues and Decision Memorandum.

[12] *See Diamond Sawblades and Parts Thereof From the People's Republic of China; Final Results of Antidumping Duty Administrative Review; 2012–2013,* 80 FR 32344 (June 8, 2015).

shipment and separate rate companies discussed above, Commerce considers all other companies for which a review was requested and which did not file a separate rate application to be part of the China-wide entity.[13]

Final Results of Administrative Review

As a result of this administrative review, Commerce determines that the following weighted-average dumping margins exist for the period November 1, 2017 through October 31, 2018:

Exporters	Weighted-average dumping margin (percent)
Chengdu Huifeng New Material Technology Co., Ltd	0.00
Separate Rate Applicable to the Following Non-Selected Companies:	
Bosun Tools Co., Ltd	0.00
Jiangsu Fengtai Single Entity	0.00
Wuhan Wanbang Laser Diamond Tools Co., Ltd	0.00
Xiamen ZL Diamond Technology Co., Ltd	0.00
Zhejiang Wanli Tools Group Co., Ltd	0.00

Disclosure

Commerce intends to disclose the calculations performed for these final results within five days of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), and the *Final Modification for Reviews,*[14] Commerce intends to instruct CBP to liquidate without regard to antidumping duties all appropriate entries for respondents eligible for a separate rate.[15] For all other companies, we will instruct CBP to apply the antidumping duty assessment rate of the China-wide entity, 82.05 percent, to all entries of subject merchandise exported by these companies.[16] For the three companies that we determined had no reviewable entries of the subject merchandise in this review period, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the China-wide rate. We intend to issue assessment instructions to CBP 15 days after the date of publication of the final results of these reviews in the **Federal Register**.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of these reviews for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For the subject merchandise exported by the companies listed above that have separate rates, the cash deposit rate will be equal to the weighted-average dumping margin established for Chengdu Huifeng in the final results of this administrative review; (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a 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(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5). Note that Commerce has temporarily modified certain of its requirements for serving documents

[13] *See Initiation Notice,* 85 FR at 2160 (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. . . .''). Companies that are subject to this administrative review that are considered to be part of the China-wide entity are: ASHINE Diamond Tools Co., Ltd.; Danyang City Ou Di Ma Tools Co. Ltd.; Danyang Huachang Diamond Tool Manufacturing Co., Ltd.; Danyang Like Tools Manufacturing Co., Ltd.; Danyang NYCL Tools Manufacturing Co., Ltd.; Danyang Tsunda Diamond Tools Co., Ltd.; Guilin Tebon Superhard Material Co., Ltd.; Hangzhou Deer King Industrial and Trading Co., Ltd.; Hangzhou Kingburg Import & Export Co., Ltd.; Hebei XMF Tools Group Co., Ltd.; Henan Huanghe Whirlwind Co., Ltd.,; Henan Huanghe Whirlwind International Co., Ltd.; Hong Kong Hao Xin International Group Limited, Hubei Changjiang Precision Engineering Materials Technology Co., Ltd.; Hubei Sheng Bai Rui Diamond Tools Co., Ltd.; Huzhou Gu's Import & Export Co., Ltd.; Jiangsu Huachang Diamond Tools Manufacturing Co., Ltd.; Jiangsu Inter-China Group Corporation; Jiangsu Youhe Tool Manufacturer Co., Ltd.; Orient Gain International Limited, Pantos Logistics (HK) Company Limited; Pujiang Talent Diamond Tools Co., Ltd.; Qingdao Hyosung Diamond Tools Co., Ltd.; Qingyuan Shangtai Diamond Tools Co., Ltd.; Qingdao Shinhan Diamond Industrial Co., Ltd.; Quanzhou Zhongzhi Diamond Tool Co., Ltd.; Rizhao Hein Saw Co., Ltd.; Saint-Gobain Abrasives (Shanghai) Co., Ltd.; Shanghai Jingquan Industrial Trade Co., Ltd.; Shanghai Starcraft Tools Co. Ltd.; Sino Tools Co., Ltd.; Wuhan Baiyi Diamond Tools Co., Ltd.; Wuhan Sadia Trading Co., Ltd.; Wuhan ZhaoHua Technology Co., Ltd.; Zhenjiang Inter-China Import & Export Co., Ltd.; ZL Diamond Technology Co., Ltd.; and ZL Diamond Tools Co., Ltd. Although Shanghai Starcraft Tools Co. Ltd. submitted comments stating that its shipments listed in the CBP import data placed on the record by Commerce were not subject merchandise, we did not treat the submission as a no-shipment statement in the *Preliminary Results* and, therefore, we preliminarily considered Shanghai Starcraft Tools Co. Ltd. to be part of the China-wide Entity. *See* the ''Preliminary Determination of No Shipments'' section of the Preliminary Decision Memorandum. We received no additional comments or information since the *Preliminary Results* and, therefore, consider Shanghai Starcraft Tools Co. Ltd. to be part of the China-wide Entity for the final results.

[14] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012) (*Final Modification for Reviews*).

[15] *See* 19 CFR 351.212(b)(1).

[16] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 2159 (February 6, 2019) (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.'')

containing business proprietary information.[17]

Dated: November 2, 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 Order
IV. Surrogate Country
V. Discussion of the Issues
  Comment 1: Selection of Primary Surrogate Country
  Comment 2: Valuation of Diamond Input
  Comment 3: Selection of Financial Statements for Surrogate Financial Ratios
  Comment 4: Whether to Apply Partial AFA to Chengdu Huifeng's Reported Labor FOPs
  Comment 5: Conversions of Surrogate Values
VI. Recommendation

[FR Doc. 2020–24800 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–DS–P

[17] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–837, A–533–828, A–588–068, A–580–852, A–201–831, A–549–820, C–533–829]

Prestressed Concrete Steel Wire Strand From Brazil, India, Japan, the Republic of Korea, Mexico, and Thailand: Continuation of the Antidumping Duty Finding/Orders and Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC) in their five year (sunset) reviews that revocation of the antidumping duty (AD) finding on prestressed concrete steel wire strand (PC strand) from Japan, and the AD orders on PC strand from Brazil, India, the Republic of Korea (Korea), Mexico, and Thailand (hereafter referred to as the six countries) would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, and that revocation of the countervailing duty (CVD) order on PC strand from India would likely lead to continuation of recurrence of net countervailable subsidies and material injury to an industry in the United States, Commerce is publishing a notice of continuation of the AD finding/orders on PC strand from the six countries and the CVD order on PC strand from India.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Samantha Kinney or Brian Smith, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2285 or (202) 482–1766, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 1978, and January 28, 2004, Commerce published in the **Federal Register** notices of the AD finding on PC strand from Japan and of the AD orders on PC strand from Brazil, India, Mexico, Korea, and Thailand, respectively.[1] On February 4, 2004, Commerce published the CVD order on PC strand from India in the **Federal Register**.[2] On March 2, 2020, Commerce initiated[3] and the ITC instituted[4] sunset reviews of the *AD Finding/Orders* on PC strand from the six countries and the *CVD Order* on PC strand from India, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its review, Commerce determined that revocation of the *AD Finding/Orders* on PC strand from the six countries would likely lead to a continuation or recurrence of dumping and that revocation of the *CVD Order* on PC strand from India would likely lead to continuation or recurrence of net countervailable subsidies, and therefore, notified the ITC of the magnitude of the margins of dumping and the subsidy rates likely to prevail should the finding/orders be revoked.[5]

On November 3, 2020, the ITC published its determination, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *AD Finding/Orders* on PC strand from the six countries, and the *CVD Order* on PC strand from India would likely lead to a continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[6]

Scope of the Order

The product covered in the sunset reviews of the AD orders on PC strand from Brazil, India, Korea, Mexico, and Thailand, and the *CVD Order* on PC strand from India is steel strand produced from wire of non-stainless, non-galvanized steel, which is suitable for use in prestressed concrete (both pre-tensioned and post-tensioned) applications. The product definition encompasses covered and uncovered strand and all types, grades, and diameters of PC strand.

The product covered in the sunset review of the AD finding on PC strand from Japan is steel wire strand, other than alloy steel, not galvanized, which is stress-relieved and suitable for use in prestressed concrete.

The merchandise subject to the *AD Finding/Orders* on PC strand from the six countries and the CVD order on PC strand from India is currently classifiable under subheadings 7312.10.3010 and 7312.10.3012 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of the *AD Finding/Orders* on PC strand from the six countries would likely lead

[1] *See Steel Wire Strand for Prestressed Concrete from Japan; Finding of Dumping,* 43 FR 57599 (December 8, 1978) conducted by the Treasury Department (at the time a determination of dumping resulted in a ''finding'' rather than the later applicable ''order''); *see also Notice of Antidumping Duty Order: Prestressed Concrete Steel Wire Strand from Brazil,* 69 FR 4112 (January 28, 2004); *Notice of Antidumping Duty Order: Prestressed Concrete Steel Wire Strand from India,* 69 FR 4110 (January 28, 2004); *Notice of Antidumping Duty Order: Prestressed Concrete Steel Wire Strand from the Republic of Korea,* 69 FR 4109 (January 28, 2004); *Notice of Antidumping Duty Order: Prestressed Concrete Steel Wire Strand from Mexico,* 69 FR 4112 (January 28, 2004); and *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Prestressed Concrete Steel Wire Strand from Thailand,* 69 FR 4111 (January 28, 2004). The AD finding on Japan and the AD orders on Brazil, India, Mexico, Korea, and Thailand are collectively referred to as *AD Finding/Orders* for purposes of this notice.

[2] *See Notice of Countervailing Duty Order: Prestressed Concrete Steel Wire Strand from India,* 69 FR 5319 (February 4, 2004) (*CVD Order*).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 12253 (March 2, 2020).

[4] *See Prestressed Concrete Steel Wire Strand from Brazil, India, Japan, Korea, Mexico, and Thailand; Institution of Five-Year Reviews,* 85 FR 12331 (March 2, 2020).

[5] *See Prestressed Concrete Steel Wire Strand from Brazil, India, Japan, Mexico, Republic of Korea and Thailand: Final Results of Expedited Sunset Reviews of the Antidumping Duty Finding and Orders,* 85 FR 39164 (June 30, 2020); *see also Prestressed Concrete Steel Wire Strand from India: Final Results of Expedited Sunset Review of Countervailing Duty Order,* 85 FR 38846 (June 29, 2020).

[6] *See Prestressed Concrete Steel Wire Strand from Brazil, India, Japan, Korea, Mexico, and Thailand,* 85 FR 69643 (November 3, 2020).

to a continuation or recurrence of dumping, and of material injury to an industry in the United States, and that revocation of the *CVD Order* on PC strand from India would likely lead to continuation or recurrence of countervailable subsidies and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the AD finding on PC strand from Japan, the AD orders on PC strand from Brazil, India, Korea, Mexico, and Thailand, and the *CVD Order* on PC strand from India. U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of the *AD Finding/Orders* and *CVD Order* will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year review of the finding/orders not later than 30 days prior to the fifth anniversary of the effective date of this continuation notice.

Notification to Interested Parties

These five-year sunset reviews and this notice are in accordance with section 751(c) of the Act and published pursuant to 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: November 3, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–24834 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–991]

Chlorinated Isocyanurates From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) has completed its administrative review of the countervailing duty (CVD) order on chlorinated isocyanurates (chlorinated isos) from the People's Republic of China (China) for the period of review (POR) January 1, 2017 through December 31, 2017, and determines that countervailable subsidies are being provided to producers and exporters of chlorinated isos. The final net subsidy rates are listed below in ''Final Results of Administrative Review.''

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Justin Neuman or Annathea Cook, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0486 or (202) 482–0250, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 13, 2014, Commerce published in the **Federal Register** a CVD order on chlorinated isos from China.[1] Pursuant to a request from the petitioners,[2] Commerce initiated this administrative review on January 31, 2019.[3] On January 16, 2020, Commerce published the *Preliminary Results* of this review in the **Federal Register**.[4] We invited interested parties to comment on the *Preliminary Results.* On April 24, 2020, Commerce exercised its discretion to toll all deadlines in administrative reviews by 50 days.[5]

On May 18, 2020, we received case briefs from the petitioners,[6] the Government of China (GOC),[7] and the mandatory respondents, Heze Huayi Chemical Co., Ltd. (Huayi) and Juancheng Kangtai Chemical Co., Ltd. (Kangtai).[8] On May 26, 2020, we received rebuttal briefs from the petitioners,[9] the GOC,[10] and the mandatory respondents, Huayi and Kangtai.[11] On June 25, 2020, Commerce extended the time period for issuing the final results to September 2, 2020.[12] On July 21, 2020, Commerce again exercised its discretion to toll all deadlines in administrative reviews by 60 days.[13]

Scope of the Order

The products covered by the order are chlorinated isocyanurates. For a complete description of the scope of the order, *see* Appendix I.

Analysis of Comments Received

All issues raised in the parties' briefs are listed in Appendix II of this notice and addressed in the Issues and Decision Memorandum.[14] 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 *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on case briefs, rebuttal briefs, and all supporting documentation, we made changes since the *Preliminary Results* with respect to the benchmark used to calculate the benefit from the provision of natural gas for less than adequate remuneration.[15]

[1] *See Chlorinated Isocyanurates from the People's Republic of China: Countervailing Duty Order,* 79 FR 67424 (November 13, 2014).

[2] The petitioners are Bio-Lab, Inc., Clearon Corp., and Occidental Chemical Corporation.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 2159 (February 6, 2019).

[4] *See Chlorinated Isocyanurates from the People's Republic of China: Preliminary Results of the Countervailing Duty Administrative Review; 2017,* 85 FR 2701 (January 16, 2020) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[5] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated April 24, 2020.

[6] *See* Petitioners' Letter, ''Case Brief of Bio-Lab, Inc., Clearon Corp., and Occidental Chemical Corporation,'' dated May 18, 2020.

[7] *See* GOC's Letter, ''GOC Case Brief—Fourth Administrative Review of the Countervailing Duty Order on Carbon and Alloy Steel Threaded Rod from the People's Republic of China (C–570–991),'' dated May 18, 2020.

[8] *See* Huayi's and Kangtai's Letter, ''Chlorinated Isocyanurates from the People's Republic of China: Case Brief,'' dated May 18, 2020.

[9] *See* Petitioners' Letter, ''Rebuttal Brief of Bio-Lab, Inc., Clearon Corp., and Occidental Chemical Corporation,'' dated May 26, 2020.

[10] *See* Government of China's Letter, ''GOC Rebuttal Brief—Fourth Administrative Review of the Countervailing Duty Order on Carbon and Alloy Steel Threaded Rod from the People's Republic of China (C–570–991),'' dated May 26, 2020.

[11] *See* Huayi's and Kangtai's Letter, ''Chlorinated Isocyanurates from the People's Republic of China: Rebuttal Brief,'' dated May 26, 2020.

[12] *See* Memorandum, ''Chlorinated Isocyanurates from the People's Republic of China: Extension of Deadline for Final Results of Countervailing Duty Administrative Review, 2017,'' dated June 25, 2020.

[13] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[14] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Administrative Review of the Countervailing Duty Order on Chlorinated Isocyanurates from the People's Republic of China; 2017,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[15] *See* Issues and Decision Memorandum at Comment 4.

Methodology

Commerce conducted this CVD review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[16] The Issues and Decision Memorandum contains a full description of the methodology underlying Commerce's conclusions, including any determination that relied upon the use of adverse facts available pursuant to sections 776(a) and (b) of the Act.

Final Results of Administrative Review

In accordance with 19 CFR 351.221(b)(5), we determine the following net subsidy rates for the 2017 administrative review:

Company	Subsidy rate (percent)
Hebei Jiheng Chemical Co., Ltd	377.60
Heze Huayi Chemical Co., Ltd	2.47
Juancheng Kangtai Chemical Co., Ltd	3.01

Assessment Rates

In accordance with 19 CFR 351.212(b)(2), Commerce intends to issue assessment instructions to U.S. Customs and Border Protection (CBP) 15 days after the date of publication of these final results of review, to liquidate shipments of subject merchandise produced and/or exported by the companies listed above, entered, or withdrawn from warehouse, for consumption on or after January 1, 2017 through December 31, 2017, at the *ad valorem* rates listed above.

Cash Deposit Instructions

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respective companies listed above. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most recent company-specific or all-others rate applicable to the company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

[16] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 2, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Order

The products covered by the order are chlorinated isocyanurates. Chlorinated isocyanurates are derivatives of cyanuric acid, described as chlorinated s-triazine triones. There are three primary chemical compositions of chlorinated isocyanurates: (1) trichlorisocyanuric acid (TCCA) ($Cl_3(NCO)_3$); (2) sodium dichlorisocyanurate (dihydrate) ($NaCl_2(NCO)_3$ X $2H_2O$); and (3) sodium dichlorisocyanurate (anhydrous) ($NaCl_2(NCO)_3$). Chlorinated isocyanurates are available in powder, granular and solid (*e.g.,* tablet or stick) forms.

Chlorinated isocyanurates are currently classifiable under subheadings 2933.69.6015, 2933.69.6021, 2933.69.6050, 3808.50.4000, 3808.94.5000, and 3808.99.9500 of the Harmonized Tariff Schedule of the United States (HTSUS). The tariff classification 2933.69.6015 covers sodium dichlorisocyanurate (anhydrous and dihydrate forms) and trichlorisocyanuric acid. The tariff classifications 2933.69.6021 and 2933.69.6050 represent basket categories that include chlorinated isocyanurates and other compounds including an unfused triazine ring. The tariff classifications 3808.50.4000, 3808.94.5000 and 3808.99.9500 cover disinfectants that include chlorinated isocyanurates. The HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of the order is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. List of Comments from Interested Parties
IV. Scope of the Order
V. Changes Since the Preliminary Results
VI. Subsidies Valuation Information
VII. Use of Facts Otherwise Available and Adverse Inferences
VIII. Programs Determined to be Countervailable
IX. Programs Determined Not to be Used or Not to Confer Measurable Benefits During the POR
X. Analysis of Comments
Comment 1: Whether the Natural Gas Market in China Is Distorted
Comment 2: Whether the Provision of Natural Gas for Less than Adequate Remuneration (LTAR) Is Specific
Comment 3: Whether Natural Gas Suppliers Are Government Authorities
Comment 4: Whether Commerce Should Select a Different Benchmark for Natural Gas for the Final Results
Comment 5: Whether Commerce Should Apply Adverse Facts Available (AFA) to the Export Buyer's Credit Program (EBCP)
Comment 6: Selection of the AFA Rate for the EBCP
Comment 7: Whether the Income Tax Deduction for Research and Development (R&D) Expenses Program Is Specific
Comment 8: Whether Commerce Should Conduct Verification
XI. Recommendation

[FR Doc. 2020–24762 Filed 11–6–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–017]

Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this sunset review, the Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on certain passenger vehicle and light truck tires (passenger tires) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 82–1785.

SUPPLEMENTARY INFORMATION:

Background

On August 10, 2015, Commerce published the CVD *Order* on passenger

tires from China.[1] On July 10, 2020, Commerce published the *Notice of Initiation* of the first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.218(c).[2] On July 16, 2020, Commerce received a notice of intent to participate from the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial Workers Union, AFL–CIO, CLC (collectively, the petitioner) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The petitioner claimed interested party status under section 771(9)(D) of the Act as a certified union representative of an industry engaged in the manufacture, production, or wholesale in the United States of a domestic like product.

On July 31, 2020, Commerce received an adequate substantive response from the petitioner within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] Commerce did not receive submissions from any other interested parties. We received no substantive response from respondent interested parties.

On August 20, 2020, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce has conducted an expedited (120-day) sunset review of the *Order.*

Scope of the Order

Imports covered by the order are shipments of certain passenger vehicle and light truck tires. Passenger vehicle and light truck tires are new pneumatic tires, of rubber, with a passenger vehicle or light truck size designation. Tires covered by this order may be tube-type, tubeless, radial, or non-radial, and they may be intended for sale to original equipment manufacturers or the replacement market. Subject tires have, at the time of importation, the symbol ''DOT'' on the sidewall, certifying that the tire conforms to applicable motor vehicle safety standards.

The merchandise subject to this order may be classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 4011.10.10.10, 4011.10.10.20, 4011.10.10.30, 4011.10.10.40, 4011.10.10.50, 4011.10.10.60, 4011.10.10.70, 4011.10.50.00, 4011.20.10.05, and 4011.20.50.10. Tires meeting the scope description may also enter under the following HTSUS subheadings: 4011.99.45.10, 4011.99.45.50, 4011.99.85.10, 4011.99.85.50, 8708.70.45.45, 8708.70.45.60, 8708.70.60.30, 8708.70.60.45, and 8708.70.60.60. Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Analysis of Comments Received

All issues raised in this sunset review are addressed 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 *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed 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 Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, we determine that revocation of the CVD order on passenger tires from China would be likely to lead to continuation or recurrence of countervailable subsidies at the following rates:

Producer/exporter	Net countervailable subsidy rate (percent)
GITI Tire (Fujian) Co., Ltd	36.79
Cooper Kunshan Tire Co., Ltd	20.73
Shandong Yongsheng Rubber Group Co., Ltd	116.73
All Others	30.61

Administrative Protective Order

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 order 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 the final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: October 29, 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 Order
IV. History of the Order
V. Legal Framework
VI. Discussion of the Issues
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2020–24812 Filed 11–6–20; 8:45 am]

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[1] *See Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 47902 (August 10, 2015) (*Order*).

[2] *See Initiation of Five-Year* (''*Sunset*'') *Review,* 85 FR 39526 (July 1, 2020).

[3] *See* Petitioner's Letter, ''Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Notice of Intent to Participate,'' dated July 16, 2020.

[4] *See* Petitioner's Letter, ''Passenger Vehicle and Light Truck Tires from China, CVD Order, First Sunset Review: Substantive Response of USW,'' dated July 31, 2020.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on July 1, 2020,'' dated August 20, 2020.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–002]

Chloropicrin From the People's Republic of China: Final Results of Sunset Review and Revocation of Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On August 4, 2020, the Department of Commerce (Commerce) initiated the fifth sunset review of the antidumping duty order on chloropicrin from the People's Republic of China (China). Because the domestic interested parties did not file a timely substantive response in this sunset review, Commerce is revoking this antidumping duty order.

DATES: Applicable September 22, 2020.

FOR FURTHER INFORMATION CONTACT: Abdul Alnoor, AD/CVD Operations,

Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4554.

SUPPLEMENTARY INFORMATION:

Background

On March 22, 1984, Commerce issued an antidumping duty order on chloropicrin from China.[1] On September 22, 2015, Commerce published a notice of continuation of the *Order*.[2] There has been one administrative review since issuance of the *Order*.[3] Commerce conducted four previous sunset reviews of the *Order*. Commerce published the final results of those sunset reviews on March 9, 1999;[4] July 6, 2004;[5] November 6, 2009;[6] and August 7, 2015.[7] On August 4, 2020, Commerce initiated the fifth sunset review of this *Order*.[8]

On August 18, 2020, within the applicable deadline, Commerce received notice of intent to participate[9] from Ashta Chemicals, Inc.; Niklor Chemical Co., Inc.; and Trinity Manufacturing, Inc., the domestic interested parties in this proceeding.[10] However, the domestic interested parties failed to submit a substantive response to the notice of initiation by the applicable time limit of September 3, 2020, as required by 19 CFR 351.218(d)(3).[11] Pursuant to 19 CFR 351.218(e)(1)(i)(C)(2), on September 10, 2020, Commerce notified the International Trade Commission, in writing, that it intended to issue a final determination revoking this antidumping duty order.[12]

Scope of the Order

The merchandise subject to the antidumping duty order is chloropicrin, also known as trichloronitromethane. A major use of the product is as a pre-plant soil fumigant (pesticide). Such merchandise is classifiable under Harmonized Tariff Schedule (HTS) subheading 2904.90.50.05.[13] The HTS subheading is provided for convenience and customs purposes. The written description remains dispositive.

Determination To Revoke

19 CFR 351.218(e)(1)(i)(C) states that if no domestic party has filed a complete substantive response to the notice of initiation under paragraph (d)(3) of that section, then Commerce will issue a final determination revoking the order or terminating the suspended investigation not later than 90 days after the date of publication in the **Federal Register** of the Notice of Initiation. In turn, paragraph (d)(3) establishes a time limit for substantive responses to a notice of initiation, which is 30 days after the date of publication in the **Federal Register** of the notice of initiation. In this case, the notice of initiation was published in the **Federal Register** on August 4, 2020, and therefore the applicable time limit for substantive responses was September 3, 2020. As noted above, Commerce did not receive a substantive response from any domestic interested party by September 3.

Because no domestic interested party timely filed an adequate substantive response in this sunset review, Commerce finds that no domestic interested party has responded to the notice of initiation of this sunset review under 751(c)(3)(A) of the Act. Therefore, consistent with the section 751(c)(3)(A) of the Act and 19 CFR 351.222(i)(1)(i), we are revoking the antidumping duty order on chloropicrin from China.[14]

Effective Date of Revocation

The effective date of revocation is September 22, 2020, the fifth anniversary of the date of publication in the **Federal Register** of the most recent notice of continuation of this antidumping duty order.[15]

Pursuant to section 751(c)(3)(A) of the Act, Commerce intends to issue instructions to U.S. Customs and Border Protection 15 days after the publication of this notice to terminate the suspension of liquidation of the merchandise subject to this order entered, or withdrawn from warehouse, on or after September 22, 2020. Entries of subject merchandise prior to the effective date of revocation will continue to be subject to suspension of liquidation and antidumping duty deposit requirements. Commerce will complete any pending administrative reviews of this order and will conduct administrative reviews of subject merchandise entered prior to the effective date of revocation in response to appropriately filed requests for review.

This notice of revocation is published in accordance with sections 751(c) and 777(i)(1) of the Act and 19 CFR 351.218(e)(1)(i)(C)(3) and 19 CFR 351.222(i)(1)(i).

Dated: November 2, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–24828 Filed 11–6–20; 8:45 am]

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[1] *See Antidumping Duty Order: Chloropicrin from the People's Republic of China,* 49 FR 10691 (March 22, 1984) (*Order*).

[2] *See Chloropicrin From the People's Republic of China: Continuation of Antidumping Duty Order,* 80 FR 57149 (September 22, 2015) (2015 Continuation Notice).

[3] *See Chloropicrin from the People's Republic of China: Final Results of Administrative Review of Antidumping Duty Order,* 50 FR 2844 (January 22, 1985).

[4] *See Final Results of Expedited Sunset Review: Chloropicrin from the People's Republic of China,* 64 FR 11440 (March 9, 1999).

[5] *See Chloropicrin from the People's Republic of China; Final Results of the Expedited Sunset Review of Antidumping Duty Order,* 69 FR 40601 (July 6, 2004).

[6] *See Chloropicrin From the People's Republic of China: Final Results of the Expedited Sunset Review of the Antidumping Duty Order,* 74 FR 57450 (November 6, 2009).

[7] *See Chloropicrin from the People's Republic of China: Final Results of the Expedited Sunset Review of the Antidumping Duty Order,* 80 FR 47467 (August 7, 2015).

[8] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 47185 (August 4, 2020).

[9] *See* Domestic Interested Parties' Letter, ''Notice of Intent to Participate in Five-Year (''Sunset'') Review of Chloropicrin from China; Application Under Administrative Protective Order,'' dated August 18, 2020.

[10] *See* 19 CFR 351.218(d)(1)(i).

[11] On September 18, 2020, the domestic interested parties attempted to file a late substantive response. *See* Domestic Interested Parties' Letter, ''Substantive Response on Behalf of Ashta Chemicals Inc, Niklor Chemical Company, and Trinity Manufacturing, Inc,'' dated September 18, 2020. At the same time, the domestic interested parties also filed an untimely request for an extension to file the substantive response in this sunset review. *See* Letter from Kalik Lewin, ''Request for Leave for late Filing: Substantive Response in Five-Year (''Sunset'') Review of Chloropicrin from China,'' dated September 18, 2020. Commerce rejected the late submission of the substantive response. *See* Commerce Letters, ''Five-Year ('Sunset') Review of Chloropicrin from China: Rejection of Request for Leave for Late Filing and Rejection of Domestic Interested Parties' Substantive Response,'' dated September 28, 2020; and ''Five-Year ('Sunset') Review of Chloropicrin from China: Response to Second Request to Extend the Deadline for Filing a Substantive Response,'' dated November 2, 2020.

[12] *See* Commerce's Letter, ''Sunset Review Initiated on August 4, 2020,'' dated September 10, 2020.

[13] Since this scope was written, the HTS subheading has changed. Subject merchandise is currently classifiable under HTS subheading 2904.91.00 00.

[14] *See* 19 CFR 351.218(e)(1)(i)(C)(1).

[15] *See* 2015 Continuation Notice.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–818]

Certain Pasta From Italy: Initiation and Preliminary Results of Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is initiating a changed circumstances review (CCR) to

determine if Newlat Food S.p.A. (Newlat) is the successor-in-interest to Delverde Industrie Alimentari S.p.A. (Delverde) in the context of the antidumping duty order on certain pasta from Italy. We preliminarily determine that Newlat is not the successor-in-interest to Delverde.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: John Hoffner, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–3315.

SUPPLEMENTARY INFORMATION:

Background

On July 14, 1996, Commerce published in the **Federal Register** an antidumping duty (AD) order on certain pasta from Italy.[1] On July 30, 2020, Newlat requested that, pursuant to section 751(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216(b), Commerce initiate and conduct a CCR of the *Order* to determine if Newlat is the successor-in-interest to Delverde. Newlat also requested that Commerce issue the preliminary results of this CCR in conjunction with the notice of initiation, as permitted under 19 CFR 315.221(c)(3)(ii).[2] The domestic industry has filed no comments in response to the request for a CCR.

Scope of the Order

Imports covered by this *Order* are shipments of certain non-egg dry pasta in packages of five pounds four ounces or less, whether or not enriched or fortified or containing milk or other optional ingredients such as chopped vegetables, vegetable purees, milk, gluten, diastasis, vitamins, coloring and flavorings, and up to two percent egg white. The pasta covered by the scope of the *Order* is typically sold in the retail market, in fiberboard or cardboard cartons, or polyethylene or polypropylene bags of varying dimensions.

Excluded from the scope of this *Order* are refrigerated, frozen, or canned pastas, as well as all forms of egg pasta, with the exception of non-egg dry pasta containing up to two percent egg white. Multicolored pasta, imported in kitchen display bottles of decorative glass that are sealed with cork or paraffin and bound with raffia, is excluded from the scope of the *Order*.[3] Pursuant to Commerce's August 14, 2009, changed circumstances review, effective July 1, 2008, gluten free pasta is also excluded from the scope of the order.[4] Effective January 1, 2012, ravioli and tortellini filled with cheese and/or vegetables are also excluded from the scope of the *Order*.[5]

Also excluded are imports of organic pasta from Italy that are certified by an EU authorized body in accordance with the United States Department of Agriculture's National Organic Program for organic products. The organic pasta certification must be retained by exporters and importers and made available to U.S. Customs and Border Protection or the Department of Commerce upon request.

The merchandise subject to this *Order* is currently classifiable under items 1901.90.90.95 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the *Order* is dispositive.

Initiation of CCR

Pursuant to section 751(b)(1)(A) of the Act and 19 CFR 351.216(d), Commerce will conduct a CCR upon receipt of a request from an interested party or receipt of information which shows changed circumstances sufficient to warrant a review of the order. The information provided by Newlat demonstrates changed circumstances sufficient to warrant a review to determine if Newlat is the successor-in-interest to Delverde, in accordance with 19 CFR 351.216(d). Therefore, in accordance with section 751(b)(1)(A) of the Act and 19 CFR 351.216(d), Commerce is initiating a CCR to determine whether Newlat is the successor-in-interest to Delverde for purposes of the *Order*.

Section 351.221(c)(3)(ii) of Commerce's regulations permits Commerce to combine the notice of initiation and the preliminary results if Commerce concludes that expedited action is warranted.[6] In this instance, because the record contains information necessary to make a preliminary finding, we find that expedited action is warranted and have combined the notice of initiation and the notice of preliminary results.[7]

Methodology

In this CCR, pursuant to section 751(b) of the Act, Commerce conducted a successor-in-interest analysis. In making a successor-in-interest determination, Commerce examines several factors, including, but not limited to, changes in the following: (1) Management; (2) production facilities; (3) supplier relationships; and (4) customer base.[8] While no single factor or combination of factors will necessarily provide a dispositive indication of succession, generally, Commerce will consider the company to be a successor to the previous company if the new company's operation is not materially dissimilar to that of its predecessor.[9] Thus, if the record evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the prior company, Commerce may assign the new company the cash deposit rate of its predecessor.[10]

[1] *See Notice of Antidumping Duty Order and Amended Final Determination of Sales at Less Than Fair Value: Certain Pasta From Italy,* 61 FR 38544 (July 24, 1996) (*Order*); *see also Notice of Second Amendment to the Final Determination and Antidumping Duty Order: Certain Pasta From Italy,* 61 FR 42231 (August 14, 1996).

[2] *See* Newlat's Letter, ''Certain Pasta from Italy—Request for Changed Circumstances Review,'' dated July 30, 2020 (Newlat CCR Request).

[3] *See* Memorandum to Richard Moreland, dated August 25, 1997, which is on file in the Central Records Unit.

[4] *See Certain Pasta from Italy: Notice of Final Results of Antidumping Duty Changed Circumstances Review and Revocation, in Part,* 74 FR 41120 (August 14, 2009).

[5] *See Certain Pasta from Italy: Final Results of Antidumping Duty and Countervailing Duty Changed Circumstances Reviews and Revocation, in Part,* 79 FR 58319, 58320 (September 29, 2014).

[6] *See Initiation and Preliminary Results of Changed Circumstances Reviews: Antidumping Duty Orders on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China and Antidumping Duty Order on Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China;* 82 FR 12558 (March 6, 2017) and accompanying Preliminary Decision Memorandum, unchanged in *Antidumping Duty Orders on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China and Antidumping Duty Orders on Certain Crystalline Silicon Photovoltaic Products from the People's Republic of China: Final Results of Changed Circumstances Reviews,* 82 FR 17797 (April 13, 2017).

[7] *See* 19 CFR 351.221(c)(3)(ii); *see also Certain Pasta from Italy: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 80 FR 33480, 33480–41 (June 12, 2015)], unchanged in *Certain Pasta from Italy: Final Results of Changed Circumstances Review,* 80 FR 48807 (August 14, 2015).

[8] *See, e.g., Ball Bearings and Parts Thereof from France: Final Results of Changed-Circumstances Review,* 75 FR 34688 (June 18, 2010), and accompanying Issues and Decision Memorandum at Comment 1.

[9] *See, e.g., Fresh and Chilled Atlantic Salmon from Norway; Final Results of Changed Circumstances Antidumping Duty Administrative Review,* 64 FR 9979, 9980 (March 1, 1999) (*Salmon from Norway*).

[10] *See, e.g., Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan: Initiation of Antidumping Duty Changed Circumstances Review,* 70 FR 17063, 17064 (April 4, 2005); and *Salmon from Norway*, 64 FR at 9980.

Preliminary Results of Changed Circumstances Review

We preliminarily determine that Newlat is not the successor-in-interest to Delverde. Record evidence submitted by Newlat indicates that the post-merger entity (*i.e.,* Newlat, which includes Delverde) does not operate as essentially the same business entity as the pre-merger Delverde with respect to the subject merchandise.[11] For the complete successor-in-interest analysis, refer to the accompanying successor-in-interest memorandum.[12]

Public Comment

In accordance with 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the case briefs, in accordance with 19 CFR 351.309(d). Parties who submit case or rebuttal briefs are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[13]

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of publication of this notice. Interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date. Parties are reminded that briefs and hearing requests are to be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System, available to registered users at *https://access.trade.gov* and that electronically filed documents must be received successfully in their entirety by 5 p.m. Eastern Time on the due date. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[14]

Consistent with 19 CFR 351.216(e), we will issue the final results of this CCR no later than 270 days after the date on which this review was initiated, or within 45 days of publication of these preliminary results if all parties agree to our preliminary finding.

Notification to Interested Parties

This notice is published in accordance with sections 751(b)(1) and 777(i)(1) of the Act and 19 CFR 351.216(b), 351.221(b) and 351.221(c)(3).

Dated: November 3, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–24835 Filed 11–6–20; 8:45 am]

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[11] *See* Newlat CCR Request.

[12] *See* Memorandum, ''Certain Pasta from Italy: Initiation and Preliminary Results of Changed Circumstances Review,'' dated concurrently with this notice.

[13] *See* 19 CFR 351.309(c)(2) and (d)(2).

[14] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020) (*Temporary Rule*); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–863]

Forged Steel Fittings From Taiwan: Rescission of Antidumping Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Both-Well Steel Fittings, Co., Ltd. (Bothwell), the sole company under review, did not have any entries during the period of review (POR) May 17, 2018 through August 31, 2019 that are subject to review. Therefore, we are rescinding this administrative review.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: George Ayache or Samuel Glickstein, 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) 482–2623 or (202) 482–5307, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 23, 2020, Commerce published its *Preliminary Results* stating its intent to preliminarily rescind this administrative review in the **Federal Register** and invited parties to comment.[1] For a discussion of events subsequent to the *Preliminary Results, see* the Issues and Decision Memorandum.[2] On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days.[3] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days.[4] The deadline for the final results of this review is now January 19, 2021.

Scope of the Order

The products covered by the scope of this order are carbon and alloy forged steel fittings, whether unfinished (commonly known as blanks or rough forgings) or finished. Such fittings are made in a variety of shapes including, but not limited to, elbows, tees, crosses, laterals, couplings, reducers, caps, plugs, bushings, unions, and outlets. Forged steel fittings are covered regardless of end finish, whether threaded, socket-weld or other end connections. The subject merchandise is currently classifiable under item numbers 7307.99.1000, 7307.99.3000, 7307.99.5045, and 7307.99.5060 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.[5]

Analysis of the Comments Received

The sole issue raised in the case and rebuttal brief submitted in this review is addressed in the Issues and Decision Memorandum. A list of the topics raised is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement

[1] *See Forged Steel Fittings from Taiwan: Preliminary Intent to Rescind the Antidumping Duty Administrative Review; 2018–2019,* 85 FR 44503 (July 23, 2020) (*Preliminary Results*).

[2] *See* Memorandum, ''Decision Memorandum for the Rescission of the Antidumping Duty Administrative Review of Forged Steel Fittings from Taiwan; 2018–2019,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[4] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[5] For a complete description of the scope of the order, *see* Issues and Decision Memorandum.

and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Rescission of Administrative Review

It is Commerce's practice to rescind an administrative review pursuant to 19 CFR 351.213(d)(3) when there are no reviewable entries of subject merchandise during the POR subject to the antidumping duty order and for which liquidation is suspended.[6] At the end of the administrative review, the suspended entries are liquidated at the assessment rate computed for the review period.[7] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry to be liquidated at the newly calculated assessment rate. As discussed in the Issues and Decision Memorandum, we find that, because all of the entries associated with Bothwell's reported sales of subject merchandise during the POR were liquidated by U.S. Customs and Border Protection (CBP), Bothwell had no reviewable entries during this POR.[8] Accordingly, we are rescinding this review pursuant to 19 CFR 351.213(d)(3).

Assessment

Because Commerce is rescinding this administrative review, we have not calculated a company-specific dumping margin for Bothwell.

Cash Deposit Requirements

As noted above, Commerce is rescinding this administrative review. Thus, we have not calculated a company-specific dumping margin for Bothwell. Therefore, entries of Bothwell's subject merchandise continue to be subject to its company-specific cash deposit rate of 116.17 percent. This cash deposit requirement shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a 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, which continues to govern business proprietary information in these segments of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(h) and 351.221(b)(5).

Dated: November 3, 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 Order
IV. Discussion of the Issue
Comment: Whether Commerce Should Rescind the Administrative Review
V. Recommendation

[FR Doc. 2020–24832 Filed 11–6–20; 8:45 am]

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[6] *See, e.g., Solid Fertilizer Grade Ammonium Nitrate from the Russian Federation: Notice of Rescission of Antidumping Duty Administrative Review,* 77 FR 65532 (October 29, 2012).

[7] *See* 19 CFR 351.212(b)(l).

[8] To the extent that record evidence suggests that additional Bothwell-produced merchandise imported into the United States from unaffiliated parties in third countries might have been sold during the POR, Bothwell's statements on the record indicate that it had no knowledge of those sales. Commerce therefore will not review those sales.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–560–826, A–570–992]

Monosodium Glutamate From the People's Republic of China and the Republic of Indonesia: Continuation of Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC) that revocation of the antidumping duty (AD) orders on monosodium glutamate (MSG) from the People's Republic of China (China) and the Republic of Indonesia (Indonesia) would likely lead to continuation or recurrence of dumping, and material injury to an industry in the United States, Commerce is publishing a notice of continuation of these AD orders.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On November 26, 2014, Commerce published the amended final affirmative determination in the less-than-fair-value (LTFV) investigation of MSG from China and the antidumping duty orders for MSG from China and Indonesia in the **Federal Register**.[1] On October 1, 2019, the ITC instituted,[2] and Commerce initiated,[3] the five-year (sunset) reviews of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its reviews, Commerce determined that revocation of the *Orders* would be likely to lead to continuation or recurrence of dumping

[1] *See Monosodium Glutamate from the People's Republic of China, and the Republic of Indonesia: Antidumping Duty Orders; and Monosodium Glutamate from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 70505 (November 26, 2014) (*Orders*); *see also Monosodium Glutamate from the People's Republic of China: Second Amended Final Determination of Sales at Less Than Fair Value and Amended Antidumping Order,* 80 FR 487 (January 6, 2015).

[2] *See Monosodium Glutamate from China and Indonesia; Institution of Five-Year Reviews,* 84 FR 52129 (October 1, 2019).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 84 FR 52067 (October 1, 2019) (*Initiation*).

and, therefore, notified the ITC of the magnitude of the margins likely to prevail should the *Orders* be revoked.[4] On October 27, 2020, the ITC published its determinations, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Orders

The product covered by these *Orders* is MSG, whether or not blended or in solution with other products. Specifically, MSG that has been blended or is in solution with other product(s) is included in this scope when the resulting mix contains 15 percent or more of MSG by dry weight. Products with which MSG may be blended include, but are not limited to, salts, sugars, starches, maltodextrins, and various seasonings. Further, MSG is included in these *Orders* regardless of physical form (including, but not limited to, in monohydrate or anhydrous form, or as substrates, solutions, dry powders of any particle size, or unfinished forms such as MSG slurry), end-use application, or packaging. MSG in monohydrate form has a molecular formula of $C_5H_8NO_4Na—H_2O$, a Chemical Abstract Service (CAS) registry number of 6106–04–3, and a Unique Ingredient Identifier (UNII) number of W81N5U6R6U. MSG in anhydrous form has a molecular formula of $C_5H_8NO_4Na$, a CAS registry number of 142–47–2, and a UNII number of C3C196L9FG. Merchandise covered by the scope of these *Orders* is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 2922.42.10.00. Merchandise subject to the *Orders* may also enter under HTS subheadings 2922.42.50.00, 2103.90.72.00, 2103.90.74.00, 2103.90.78.00, 2103.90.80.00, and 2103.90.90.91. The tariff classifications, CAS registry numbers, and UNII numbers are provided for convenience and customs purposes; however, the written description of the scope is dispositive.[6]

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of the *Orders* would likely lead to a continuation or a recurrence of dumping and of material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the *Orders.* U.S. Customs and Border Protection will continue to collect AD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of the *Orders* will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year review of the *Orders* not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return/destruction or conversion to judicial protective order of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Failure to comply is a violation of the APO which may be subject to sanctions.

Notification to Interested Parties

These five-year (sunset) reviews and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and published in accordance with section 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: November 3, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–24831 Filed 11–6–20; 8:45 am]

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[4] *See Monosodium Glutamate from People's Republic of China: Final Results of the First Expedited Sunset Review of the Antidumping Duty Order,* 85 FR 5616 (January 31, 2020.); *see also Monosodium Glutamate from Indonesia: Final Results of the First Full Sunset Review,* 85 FR 34419 (June 4, 2020).

[5] *See Monosodium Glutamate from China and Indonesia (Review),* 85 FR 68089 (October 27, 2020); (*Inv. Nos. 731–TA–1229–1230*).

[6] *See Monosodium Glutamate from the People's Republic of China: Second Amended Final Determination of Sales at Less Than Fair Value and Amended Antidumping Order,* 80 FR 487 (January 6, 2015).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–124]

Certain Vertical Shaft Engines Between 99cc and Up to 225cc, and Parts Thereof, From the People's Republic of China: Postponement of Final Determination of Sales at Less Than Fair Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is postponing the deadline for issuing the final determination in the less-than-fair-value (LTFV) investigation of certain vertical shaft engines between 99cc and up to 225cc, and parts thereof (small vertical engines) from the People's Republic of China (China) until March 5, 2021, and is extending the provisional measures from a four-month period to a period of not more than six months.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Whitley Herndon or Benjamin A. Luberda, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6274 or (202) 482–2185, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 7, 2020, Commerce initiated an LTFV investigation of imports of small vertical engines from China.[1] The period of investigation is July 1, 2019 through December 31, 2019. On October 21, 2020, Commerce published its *Preliminary Determination* in this LTFV investigation of small vertical engines from China.[2]

Postponement of Final Determination

Section 735(a)(2) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(2) provide that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary

[1] *See Certain Vertical Shaft Engines Between 99cc and Up to 225cc, and Parts Thereof from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 85 FR 20670 (April 14, 2020).

[2] *See Certain Vertical Shaft Engines Between 99cc and Up To 225cc, and Parts Thereof, from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, and Preliminary Affirmative Determination of Critical Circumstances, in Part,* 85 FR 66932 (October 21, 2020) (*Preliminary Determination*).

determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by the exporters or producers who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Further, 19 CFR 351.210(e)(2) requires that such postponement requests by exporters be accompanied by a request for extension of provisional measures from a four-month period to a period of not more than six months, in accordance with section 733(d) of the Act.

On October 16, 2020, and October 19, 2020, Chongqing Kohler Engines Ltd. and its ultimate parent company, Kohler Co. (collectively, Kohler), and Chongqing Zongshen General Power Machine Co., Ltd. (Chongqing Zongshen) and its affiliates (collectively, the Zongshen Companies), the mandatory respondents in this investigation, requested that Commerce postpone the deadline for the final determination until no later than 135 days from the publication of the *Preliminary Determination* and extend the application of the provisional measures from a four-month period to a period of not more than six months.[3] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination was affirmative; (2) the request was made by the exporters and producers who account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination until no later than 135 days after the date of the publication of the *Preliminary Determination* and extending the provisional measures from a four-month period to a period of not more than six months. Accordingly, Commerce will issue its final determination no later than March 5, 2021.

This notice is issued and published pursuant to 19 CFR 351.210(g).

Dated: November 3, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–24833 Filed 11–6–20; 8:45 am]

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[3] *See* Kohler's Letter, ''Certain Vertical Shaft Engines Between 99cc and 225 from the People's Republic of China: Request to Postpone Final Determination,'' dated October 16, 2020; and the Zongshen Companies' Letter, ''Certain Vertical Shaft Engines Between 99cc and Up To 225cc, and Parts Thereof, from China; AD Investigation; Zongshen Request for Postponement of Final Determination and Extension of Provisional Measures Period,'' dated October 19, 2020.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–830]

Steel Concrete Reinforcing Bar From the Republic of Turkey: Rescission of Countervailing Duty Administrative Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on steel concrete reinforcing bar (rebar) from the Republic of Turkey (Turkey), covering the period January 1, 2019, through December 31, 2019.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Peter Shaw, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0697.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2020, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the CVD order on rebar from Turkey.[1] On July 30, 2020, the Rebar Trade Coalition (the petitioner) timely requested that Commerce conduct an administrative review of for Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S (Habas).[2] We received no other requests for review. On September 3, 2020, Commerce published in the **Federal Register** a notice of initiation of an administrative review with respect to Habas, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[3] On September 6, 2020, Habas notified Commerce that it had no sales, shipments or entries of subject merchandise during the period of review (POR).[4] On September 29, 2020, Commerce issued a no shipment inquiry to U.S. Customs and Border Protection (CBP) to corroborate Habas' claim.[5] On October 2, 2020, Commerce notified all interested parties that CBP found no evidence of shipments of subject merchandise produced and exported by Habas during the POR.[6] On October 7, 2020, Commerce provided all parties an opportunity to comment on CBP's findings.[7] No parties submitted comments.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of a CVD order where it concludes that there were no reviewable entries of subject merchandise during the POR.[8] Normally, upon completion of an administrative review, the suspended entries are liquidated at the CVD assessment rate for the review period. *See* 19 CFR 351.212(b)(2). Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that Commerce can instruct CBP to liquidate at the calculated CVD assessment rate for the review period.[9] As noted above, CBP confirmed that there were no entries of subject merchandise during the POR with respect to Habas, the only company subject to this review. Accordingly, in the absence of reviewable, suspended entries of subject merchandise during the POR, we are rescinding this administrative review, in its entirety, in accordance with 19 CFR 351.213(d)(3).

Assessment Rates

Commerce will instruct CBP to assess CVDs on all appropriate entries.

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 85 FR 39531 (July 1, 2020).

[2] *See* Petitioner's Letter, ''Steel Concrete Reinforcing Bar from the Republic of Turkey: Request for Administrative Review,'' dated July 30, 2020.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 54983 (September 3, 2020) (*Initiation Notice*).

[4] *See* Habas' Letter, ''Steel Concrete Reinforcing Bar from Turkey; Habas No Shipment Letter,'' dated September 6, 2020.

[5] *See* Customs Instructions Message 0273403, dated September 29, 2020.

[6] *See* Memorandum, ''Steel Concrete Reinforcing Bar from the Republic of Turkey (C–489–830): No shipment inquiry with respect to the companies listed below during the period 01/01/2019, through 12/31/2019,'' dated October 2, 2020.

[7] *See* Memorandum, ''Steel Concrete Reinforcing Bar from the Republic of Turkey: Deadline for Comments on Results of No Shipment Inquiry,'' dated October 7, 2020.

[8] *See, e.g., Certain Hardwood Plywood Products from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review and Rescission of Review, in Part; 2017–2018,* 84 FR 54844, 54845 and n.8 (October 11, 2019) (citing *Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review; 2015,* 82 FR 14349 (March 20, 2017)).

[9] *See* 19 CFR 351.213(d)(3).

Because Commerce is rescinding this review in its entirety, the entries to which this administrative review pertained shall be assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register**.

Notification Regarding Administrative Protective Order

This notice also serves as a final 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, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of the APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with regulations and terms of an APO is a violation, which is subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(d)(4).

Dated: November 3, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–24767 Filed 11–6–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–887]

Tetrahydrofurfuryl Alcohol From the People's Republic of China: Continuation of Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC) that revocation of the antidumping duty (AD) order on tetrahydrofurfuryl alcohol (THFA) from the People's Republic of China (China) would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, Commerce is publishing a notice of continuation of the AD order.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Kate Sliney, Office III, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2437.

SUPPLEMENTARY INFORMATION:

Background

On August 6, 2004, Commerce published the AD order on THFA from China.[1] On March 1, 2020 Commerce initiated the third sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930 as amended (the Act).[2] As a result of its review, Commerce determined that revocation of the *Order* would likely lead to the continuation or recurrence of dumping and, therefore, notified the ITC of the magnitude of the margin rates likely to prevail should the *Order* be revoked.[3]

On November 2, 2020, the ITC published its determination, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Order* would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[4]

Scope of the Order

The product covered by this *Order* is THFA from China; a primary alcohol, THFA is a clear, water white to pale yellow liquid. THFA is a member of the heterocyclic compounds known as furans and is miscible with water and soluble in many common organic solvents. THFA is currently classifiable in the Harmonized Tariff Schedules of the United States (HTSUS) under subheading 2932.13.00.00. Although the HTSUS subheadings are provided for convenience and for customs purposes, Commerce's written description of the merchandise subject to the *Order* is dispositive.

Continuation of the Order

As a result of the determinations by Commerce and the ITC that revocation of the *Order* would likely lead to the continuation or a recurrence of dumping, as well as material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the *Order* on THFA from China.

U.S. Customs and Border Protection will continue to collect AD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of the *Order* will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year review of the *Order* not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Notification to Interested Parties

This five-year sunset review and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and published in accordance with section 777(i)(1) of the Act and 19 CFR 351.218(f)(4).

Dated: November 2, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–24763 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–848, C–533–849]

Commodity Matchbooks From India: Continuation of Antidumping and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC) that revocation of the antidumping duty (AD) and countervailing duty (CVD) orders on commodity matchbooks (matchbooks) from India would likely lead to continuation or recurrence of dumping, countervailable subsidies, and material injury to an industry in the United States, Commerce is publishing a notice of continuation of these AD and CVD orders.

DATES: Applicable November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Ian Hamilton, AD/CVD Operations, Enforcement and Compliance,

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[1] *See Antidumping Duty Order: Tetrahydrofurfuryl Alcohol from The People's Republic of China,* 69 FR 47911 (August 6, 2004) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 12253 (March 2, 2020).

[3] *See Tetrahydrofurfuryl Alcohol from the People's Republic of China: Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order,* 85 FR 40969 (July 8, 2020).

[4] *See Tetrahydrofurfuryl Alcohol From China,* 85 FR 69358 (November 2, 2020).

International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4798.

SUPPLEMENTARY INFORMATION:

Background

On December 11, 2009, Commerce published the AD and CVD orders on matchbooks from India.[1] On March 2, 2020, the ITC instituted,[2] and Commerce initiated,[3] the second five-year (sunset) reviews of these AD and CVD orders, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its reviews, Commerce determined that revocation of the *Orders* would be likely to lead to continuation or recurrence of dumping and countervailable subsidies and, therefore, notified the ITC of the magnitude of the margins and net subsidy rates likely to prevail should the *Orders* be revoked.[4] On November 3, 2020, the ITC published its determinations, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Orders

The scope of the *Orders* covers commodity matchbooks, also known as commodity book matches, paper matches or booklet matches.[6] Commodity matchbooks typically, but do not necessarily, consist of twenty match stems which are usually made from paperboard or similar material tipped with a match head composed of any chemical formula. The match stems may be stitched, stapled or otherwise fastened into a matchbook cover of any material, on which a striking strip composed of any chemical formula has been applied to assist in the ignition process.

Commodity matchbooks included in the scope of these *Orders* may or may not contain printing. For example, they may have no printing other than the identification of the manufacturer or importer. Commodity matchbooks may also be printed with a generic message such as ''Thank You'' or a generic image such as the American Flag, with store brands (*e.g.,* Kroger, 7-Eleven, Shurfine or Giant); product brands for national or regional advertisers such as cigarettes or alcoholic beverages; or with corporate brands for national or regional distributors (*e.g.,* Penley Corp. or Diamond Brands). They all enter retail distribution channels. Regardless of the materials used for the stems of the matches and regardless of the way the match stems are fastened to the matchbook cover, all commodity matchbooks are included in the scope of these orders. All matchbooks, including commodity matchbooks, typically comply with the United States Consumer Product Safety Commission (CPSC) Safety Standard for Matchbooks, codified at 16 CFR 1202.1 *et seq*.

The scope of these *Orders* excludes promotional matchbooks, often referred to as ''not for resale,'' or ''specialty advertising'' matchbooks, as they do not enter into retail channels and are sold to businesses that provide hospitality, dining, drinking or entertainment services to their customers, and are given away by these businesses as promotional items. Such promotional matchbooks are distinguished by the physical characteristic of having the name and/or logo of a bar, restaurant, resort, hotel, club, café/coffee shop, grill, pub, eatery, lounge, casino, barbecue or individual establishment printed prominently on the matchbook cover. Promotional matchbook cover printing also typically includes the address and the phone number of the business or establishment being promoted.[7] Also excluded are all other matches that are not fastened into a matchbook cover such as wooden matches, stick matches, box matches, kitchen matches, pocket matches, penny matches, household matches, strike-anywhere matches (aka ''SAW'' matches), strike-on-box matches (aka ''SOB'' matches), fireplace matches, barbeque/grill matches, fire starters, and wax matches.

The merchandise subject to these *Orders* is properly classified under subheading 3605.00.0060 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under subheading 3605.00.0030 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of these *Orders* is dispositive.

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of the *Orders* would likely lead to a continuation or a recurrence of dumping and countervailable subsidies and of material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the *Orders.* U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of the *Orders* will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year review of the *Orders* not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return/destruction or conversion to judicial protective order of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Failure to comply is a violation of the APO which may be subject to sanctions.

Notification to Interested Parties

These five-year (sunset) reviews and this notice are in accordance with sections 751(c) of the Act and published in accordance with section 777(i) of the Act, and 19 CFR 351.218(f)(4). Note that Commerce has modified certain of its requirements for serving documents

[1] *See Commodity Matchbooks from India: Antidumping Duty Order,* 74 FR 65737 (December 11, 2009); *see also Commodity Matchbooks from India: Countervailing Duty Order,* 74 FR 65740 (December 11, 2009) (collectively, *Orders*).

[2] *See Commodity Matchbooks from India; Institution of Five-Year Reviews,* 85 FR 12334 (March 2, 2020).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 12253 (March 2, 2020).

[4] *See Commodity Matchbooks from India: Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order,* 85 FR 36834 (June 18, 2020), and accompanying Issues and Decision Memorandum (IDM); *see also Commodity Matchbooks from India: Final Results of the Second Expedited Sunset Review of the Countervailing Duty Order,* 85 FR 41558 (July 10, 2020), and accompanying IDM.

[5] *See Commodity Matchbooks from India (Inv. Nos. 701–TA–459 and 731–TA–1155 (Review)),* 85 FR 69643 (November 3, 2020); *see also Commodity Matchbooks from India (Inv. Nos. 701–TA–512 and 731–TA–1248 (Review)),* USITC Pub. 5131 (October 2020).

[6] Such commodity matchbooks are also referred to as ''for resale'' because they always enter into retail channels, meaning businesses that sell a general variety of tangible merchandise, *e.g.,* convenience stores, supermarkets, dollar stores, drug stores and mass merchandisers.

[7] The gross distinctions between commodity matchbooks and promotional matchbooks may be summarized as follows: (1) If it has no printing, or is printed with a generic message such as ''Thank You'' or a generic image such as the American Flag, or printed with national or regional store brands or corporate brands, it is commodity; (2) if it has printing, and the printing includes the name of a bar, restaurant, resort, hotel, club, café/coffee shop, grill, pub, eatery, lounge, casino, barbecue, or individual establishment prominently displayed on the matchbook cover, it is promotional.

containing business proprietary information, until further notice.[8]

Dated: November 3, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–24830 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA559]

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permit

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

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application contains all of the required information and warrants further consideration. This Exempted Fishing Permit would allow commercial fishing vessels to participate in a sampling survey in the eastern Gulf of Maine targeting adult cod with rod and reel while on commercial lobster trips. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notice to provide interested parties the opportunity to comment on Exempted Fishing Permit applications.

DATES: Comments must be received on or before *November 24, 2020.*

ADDRESSES: You may submit written comments by either of the following methods:

- *Email: nmfs.gar.efp@noaa.gov.* Include in the subject line ''Comments on MCCF Eastern Gulf of Maine Cod Survey EFP.''
- *Mail:* Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on MCCF Eastern Gulf of Maine Cod Survey EFP.''

FOR FURTHER INFORMATION CONTACT: Spencer Talmage, Fishery Management Specialist, 978–281–9232, *Spencer.Talmage@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Maine Center for Coastal Fisheries (MCCF) submitted a complete application for an Exempted Fishing Permit (EFP) in support of an Atlantic cod biological sampling initiative in the eastern Gulf of Maine (GOM). The EFP would exempt commercial fishing vessels from gear requirements for vessels fishing under the open access Handgear B permit, which prohibit vessels from using or possessing onboard gear other than handgear while fishing for Northeast multispecies at 50 CFR 648.88(a)(2)(i), and the open access handgear possession limits specific in § 648.88(a)(1) for Gulf of Maine cod.

MCCF also requested that the EFP include an exemption from Vessel Trip Reporting (VTR) requirements at § 648.7(b)(1)(i). An exemption from these requirements would encourage participation in the EFP by vessels which would need to acquire an open access Handgear B permit to do so and are not already subject to VTR requirements. We do not intend to issue this exemption, as it is not essential to the completion of the project, and would undermine a fundamental reporting requirement of the Northeast Multispecies Fishery Management Plan.

Activity under this EFP would occur from October through April 2021, within a subset of statistical area 512, from approximately Port Clyde to Swan's Island, Maine, out to the Federal Lobster Area 1 boundary. During EFP trips, vessels would deploy commercial lobster traps as normal and would opportunistically fish with handgear for cod sampling when captains deem appropriate based on operational factors such as weather conditions and haul schedules. Vessels would record location, gear, bait, bottom type, depth, and time for each deployment of hook gear. There are two depth strata, 0–50 fathoms (0–91.4 m) and 50–100 fathoms (91.4–182.9 m). On each EFP trip, vessels would be allowed to keep up to 2 cod at or above a minimum size of 24 inches (60.9 cm) from each depth strata. Any other fish caught while fishing with handgear would be returned to the ocean as soon as possible.

Kept cod would be landed and delivered to the MCCF in Stonington. MCCF technicians would photograph, measure, and dissect each fish. MCCF would send tissue, stomach, and otolith samples will be distributed to University of Maine and the Northeast Fisheries Science Center.

The total sample size for the project is 40 cod, 20 of which would come from a 0–50-fathom (0–91.4-m) depth strata and the other 20 from a 50–100-fathom (91.4–182.9-m) depth strata. MCCF estimates that landed cod will amount to approximately 300 lb (136.1 kg) of fish for the entire sampling season, based on an assumption that the average target fish would weigh around 5 lb (2.3 kg). MCCF has stated that estimated discards would be minimal, based on experience from the Sentinel Survey Fishery. Because the maximum number of fish planned to be kept for each trip is 4 fish (2 from each strata), at least 10 EFP trips would need to occur to collect 40 cod. It is not likely that vessels will be able to catch the maximum number of cod allowed for each trip, so MCCF has projected that it may take up to 84 trips total to complete sampling. This projection assumes that each of the three vessels would make three attempts every week of the seven-month study period. Additional handgear B vessels may be added to the EFP, if approved, to meet sampling targets.

The exemption from gear requirements of the open access Handgear B permit at 50 CFR part 648.88(a)(2)(i) would allow participating vessels to deploy handgear and fish under the conditions of the permit while also fishing with pot/trap gear during commercial lobster trips. Exemptions from the open access handgear B possession limits specified in § 648.88(a)(1) for GOM cod would allow participating vessels to keep cod in excess of 25 lb (11.3 kg) per trip if needed for biological sampling.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the year. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 4, 2020.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–24837 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–22–P

[8] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA620]

Marine Mammals; Issuance of Permits

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

ACTION: Notice; issuance of permits.

SUMMARY: Notice is hereby given that individuals and institutions have been issued Letters of Confirmation (LOCs) for activities conducted under the General Authorization for Scientific Research on marine mammals. See **SUPPLEMENTARY INFORMATION** for a list of names and address of recipients.

ADDRESSES: The LOCs and related documents are available for review upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Amy Hapeman (LOC Nos. 19430, 23970), Carrie Hubard (LOC No. 22291), Jordan Rutland (LOC Nos. 23673, 23772, 23782), Courtney Smith (LOC Nos. 18689, 18959, 19826, 23546), and Sara Young (LOC No. 23253), at (301) 427–8401.

SUPPLEMENTARY INFORMATION: The requested LOCs have been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216). The General Authorization allows for bona fide scientific research that may result only in taking by Level B harassment of marine mammals. The following LOCs were issued in Fiscal Year 2020 (October 1, 2019–September 30, 2020).

File No. 23253: Issued to Pacific Mammal Research (Principal Investigator [PI]: Cindy Elliser, Ph.D.), 1513 A Avenue, Anacortes, Washington, 98221, on December 23, 2019, this study supplements current land-based visual and photo-identification/behavior surveys with boat-based photo-identification/behavior surveys and unmanned aircraft systems (UAS) surveys for population monitoring of harbor porpoise (*Phocoena phocoena*) and harbor seals (*Phoca vitulina*) in the inland waters of Washington. The LOC expires on December 31, 2024.

File No. 18689: The LOC, held by the Wild Dolphin Project (PI: Denise Herzing, Ph.D.), P.O. Box 8436, Jupiter, Florida 33468, was extended on January 30, 2020, for approximately 6 months while the holder's new application (File No. 23673) was in process (see below). The LOC authorized vessel surveys, photo-identification, and behavioral observations on bottlenose (*Tursiops truncatus*) and Atlantic spotted (*Stenella frontalis*) dolphins and 12 other range-wide, non-Endangered Species Act (ESA) listed cetacean species within the coastal and offshore waters of southeast Florida. The objectives of the research did not change. This LOC was subsequently terminated on May 26, 2020, when a new LOC (No. 23673; see below) was issued to Dr. Herzing.

File No. 18959: The LOC, held by Ruth Carmichael, Ph.D., Dauphin Island Sea Lab, 101 Bienville Blvd., Dauphin Island, Alabama 36528, was extended on March 5, 2020, for approximately 3 months while the holder's new application (File No. 23772) was in process (see below). The LOC authorized vessel-based surveys of bottlenose dolphins for behavioral observations, photo-identification, and photography/videography. The objectives are to determine population dynamics, abundance, movement patterns, social structure, and behavioral patterns of bottlenose dolphins in the northern Gulf of Mexico. This LOC was subsequently terminated on June 16, 2020, when a new LOC (No. 23772; see below) was issued to Dr. Carmichael.

File No. 23546: Issued to Donna Hauser, Ph.D., University of Alaska Fairbanks, 2160 Koyukuk Drive, P.O. Box 757340, Fairbanks, Alaska 99775, on March 24, 2020. The LOC authorizes the close approach of spotted seals (*Phoca largha*) in coastal haulouts in the Chukchi and Beaufort Seas of northern Alaska using ground and UAS surveys to conduct photo-identification, behavioral observations and monitoring, and remote video monitoring. Research objectives are to investigate the distribution, habitat use, foraging ecology, health, population structure, behavior, and abundance. Scat, spew, shed skin or hair may also be collected. The LOC expires on April 1, 2025.

File No. 23673: Issued to the Wild Dolphin Project (PI: Denise Herzing, Ph.D.), on May 26, 2020, to conduct vessel-based surveys for counts, photo-identification, photography, and observation on 13 species: Atlantic spotted, bottlenose, Fraser's (*Lagenorhyncus hosei*), pantropical spotted (*Stenella attenuatta*), Risso's (*Grampus griseus*), spinner (*Stenella longirostris*), striped (*Stenella coeruleoalba),* and unidentified lagenorhynchine (*Lagenorhyncus spp.*) dolphins; false killer (*Pseudorca crassidens*), unidentified beaked (*Ziphius cavirostris* and *Mesoplodon spp.*), long-finned pilot (*Globicephala melas*), short-finned pilot (*Globicephala macrorhynchus*), and unidentified *Kogia* (dwarf or pygmy sperm whale; *Kogia spp.*) whales. Research will take place within Florida waters of the Atlantic Ocean and Gulf of Mexico from Martin County through the Florida Keys including in the Intracoastal Waterway, coastal waters, and offshore waters. The LOC expires on May 31, 2025.

File No. 23772: Issued to Ruth Carmichael, Ph.D., Dauphin Island Sea Lab, on June 16, 2020, to conduct vessel-based surveys of bottlenose dolphins for behavioral observations, photo-identification, and photography/videography. The objectives are to determine population dynamics, abundance, movement patterns, social structure, and behavioral patterns of bottlenose dolphins in the northern Gulf of Mexico. This LOC expires June 30, 2020.

File No. 19430: The LOC, held by Jonathan Scordino, Makah Tribe, Makah Fisheries Management, P.O. Box 115, 150 Resort Drive, Neah Bay, WA 98357, was extended on July 21, 2020, for approximately 2 months while the holder's new application (File No. 23970, see below) was in process. The LOC authorizes vessel surveys of cetaceans and vessel and ground surveys (including scat collection) of pinnipeds in Washington State, with the primary study area at the northwest tip of the Olympic Peninsula. The purposes of the research are to: (1) Document the abundance and seasonal distribution patterns of marine mammals in this area, (2) determine diet overlap between certain marine mammal species and fisheries, (3) analyze scat for saxitoxin and domoic acids from harmful algal blooms, and (4) monitor the rate and cause of entanglements for pinnipeds. The extended LOC expired on September 30, 2020.

File No. 19826: The LOC, issued to Deanna Rees, U.S. Navy, Naval Facilities Engineering Command Atlantic, 6500 Hampton Blvd., Norfolk, Virginia 23508, was extended on July 21, 2020, for approximately 4 months so that the researchers can complete their field season conducting ground surveys, photo-identification, and behavioral observations of gray (*Halichoerus grypus grypus*), harbor, and harp (*Phoca groenlandica*) seals in the lower Chesapeake Bay, Virginia, and Narragansett Bay, Rhode Island waters. The purpose of the research is to investigate site fidelity and movement among haul-out locations, and to improve baseline knowledge of pinniped occurrence in areas adjacent to

Navy training and testing areas. The extended LOC expires on May 31, 2021.

File No. 22291: Issued to Barbara Brunnick, Ph.D., Palm Beach Dolphin Project, Taras Oceanographic Foundation, 5905 Stonewood Court, Jupiter, Florida 33468, on June 30, 2020, to conduct vessel surveys for photo-identification, behavioral observations, photography, and videography of cetaceans in the near shore coastal waters of Palm Beach and Martin Counties, Florida. The objectives of the research are to document the abundance, distribution, population dynamics, health, and habitat utilization of bottlenose dolphins and Atlantic spotted dolphins within the study area. Other cetacean species that may be studied if encountered are: Clymene dolphin (*Stenella clymene*), dwarf and pygmy sperm whales, melon-headed whale (*Peponocephala electra*), pantropical spotted dolphin, rough-toothed dolphin (*Steno bredanensis*), short-beaked common dolphin (*Delphinus delphis delphis*), short-finned pilot whale, spinner dolphin, and striped dolphin. The LOC expires on June 30, 2025.

File No. 23782: Issued to Janet Mann, Ph.D., Georgetown University, Reiss Science Room 406, 3700 O St. NW, Washington, DC 20057, on June 30, 2020 to conduct vessel-based surveys for behavioral observations, photo-identification, passive acoustics, UAS operations, and photography/videography of bottlenose dolphins in the Potomac River off the Northern Neck of Virginia. The objectives are to estimate seasonal abundance, habitat use, ranging patterns, seasonal site fidelity, dolphin-human interactions, behavioral ecology, and social structure of bottlenose dolphins. The LOC expires on June 30, 2025.

File No. 23970: Issued to Jonathan Scordino, Makah Tribe, Makah Fisheries Management, on September 30, 2020, to conduct (1) vessel surveys of 20 cetacean species for close approach; photography/video; photo-identification; behavioral observations; sloughed skin and feces collection; and focal follows in waters from California to Washington and Alaska; and (2) vessel and ground surveys of 6 pinniped species for counts, close approach, photography/video, behavioral observations, and scat collection in Washington waters. The objective is to document marine mammal abundance, seasonal distribution patterns, vital rates, diet, mixing ratios, genetics, and interactions with humans. The LOC replaces No. 19430 and expires on September 30, 2025.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: November 4, 2020.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–24816 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Solicitation of Applications for the Ocean Exploration Advisory Board (OEAB)

AGENCY: Office of Ocean Exploration and Research (OER), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Solicitation of applications.

SUMMARY: NOAA is soliciting applications to fill up to four membership vacancies on the Ocean Exploration Advisory Board (OEAB).

DATES: Application materials must be received no later than December 9, 2020.

ADDRESSES: Submit application materials to Christa Rabenold via email: *christa.rabenold@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: David McKinnie, OEAB Designated Federal Officer: 206–526–6950; *david.mckinnie@noaa.gov.*

SUPPLEMENTARY INFORMATION: NOAA is soliciting applications to fill up to four vacancies on the OEAB with individuals demonstrating expertise in areas of scientific research relevant to ocean exploration, including marine archaeology, or ocean-science education and communication. Representatives of other federal agencies involved in ocean exploration are encouraged to apply. The new OEAB members will serve initial three-year terms, renewable once.

The purpose of the OEAB is to advise the NOAA Administrator on matters pertaining to ocean exploration. The OEAB functions as an advisory body in accordance with the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App., with the exception of section 14. It reports to the NOAA Administrator, as directed by 33 U.S.C. 3405.

The OEAB consists of approximately ten members, including a chair and co-chair(s), designated by the NOAA Administrator in accordance with FACA requirements and the terms of the approved OEAB Charter.

The OEAB was established:

(1) To advise the Administrator on priority areas for survey and discovery;

(2) To assist the program in the development of a five-year strategic plan for the fields of ocean, marine, and Great Lakes science, exploration, and discovery;

(3) To annually review the quality and effectiveness of the proposal review process established under section 12003(a)(4); and

(4) To provide other assistance and advice as requested by the Administrator.

OEAB members are appointed as special government employees (SGEs) and will be subject to the ethical standards applicable to SGEs. Members are reimbursed for actual and reasonable expenses incurred in performing such duties but will not be reimbursed for their time. All OEAB members serve at the discretion of the NOAA Administrator.

The OEAB meets three to four times each year, exclusive of subcommittee, task force, and working group meetings.

As a Federal Advisory Committee, the OEAB's membership is required to be balanced in terms of viewpoints represented and the functions to be performed as well as including the interests of geographic regions of the country and the diverse sectors of our society.

For more information about the OEAB, visit *https://oeab.noaa.gov.*

Although the OEAB reports directly to the NOAA Administrator, OER, which is part of the NOAA Office of Oceanic and Atmospheric Research, provides staffing and other support for the OEAB. OER's mission is to explore the ocean for national benefit.

OER:

- Explores the ocean to make discoveries of scientific, economic, and cultural value, with priority given to the U.S. Exclusive Economic Zone and Extended Continental Shelf.
- Promotes technological innovation to advance ocean exploration.
- Provides public access to data and information.
- Encourages the next generation of ocean explorers, scientists, and engineers.
- Expands the national ocean exploration program through partnerships.

For more information about OER, please visit *https://oceanexplorer.noaa.gov.*

Applications: An application is required to be considered for OEAB membership. To apply, please submit (1) your full name, title, institutional affiliation, and contact information (mailing address, email address, telephone and fax numbers) with a short description of your qualifications relative to the statutory purpose of the OEAB and the ocean exploration act established under 33 U.S.C. 3401 *et seq.*; (2) a resume or curriculum vitae (maximum length four pages); and (3) a cover letter stating your interest in serving on the OEAB and highlighting specific areas of expertise relevant to the purpose of the OEAB.

Dated: October 8, 2020.

David Holst,

Director Chief Financial Officer/CAO, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2020–24045 Filed 11–6–20; 8:45 am]

BILLING CODE 3510–KA–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket DARS–2020–0041; OMB Control Number 0704–0525]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement; Prohibition of Foreign Commercial Satellite Services From Certain Foreign Entities-Representations

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension and revision of an approved information collection requirement.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, DoD announces the proposed extension and revision of a public information collection requirement and seeks public comment on the provisions thereof. *DoD invites comments on:* Whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection requirement for use through March 31, 2021. DoD proposes that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD will consider all comments received by January 8, 2021.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0525, using any of the following methods:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

○ *Email: osd.dfars@mail.mil.* Include OMB Control Number 0704–0525 in the subject line of the message.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Kimberly Bass, 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.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Bass, 571–372–6174.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS), Prohibition on Acquisition of Commercial Satellite Services from Certain Foreign Entities-Representations; OMB Control Number 0704–0525.

Type of Request: Revision and extension of a currently approved collection.

Obligation to Respond: Required to obtain or retain benefits.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Number of Respondents: 235.

Responses per Respondent: 1.

Annual Responses: 235.

Average Burden per Response: .25 hours.

Annual Burden Hours: 58.

Frequency: On Occasion.

Needs and Uses: DFARS provision 252.225–7049, Prohibition on Acquisition of Commercial Satellite Services from Certain Foreign Entities-Representations, is used by contracting officers to determine whether the offeror is subject to the statutory prohibition on award of contracts for commercial satellite services to certain foreign entities. The provision is included in solicitations for the acquisition of foreign commercial satellite services and requires the offeror to represent whether it is or is not a foreign entity subject to the prohibitions of the statute, or is or is not offering foreign commercial satellite services provided by such a foreign entity. If the offeror responds affirmatively to any of the representations, then the offeror must provide further information.

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2020–24857 Filed 11–6–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

List of Approved "Ability-to-Benefit" (ATB) Tests and Passing Scores

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: This notice provides an update to the list of ATB tests approved by the Secretary.

FOR FURTHER INFORMATION CONTACT: Aaron Washington, U.S. Department of Education, 400 Maryland Avenue SW, Room 294–12, Washington, DC 20202. Telephone: (202) 453–7241. Email: *Aaron.Washington@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: In order for a student who does not have a high school diploma or its recognized equivalent to be eligible for title IV, program assistance and who first enrolled in any title IV eligible postsecondary program on or after July 1, 2012, the student must successfully complete one of the ATB alternatives, including passing an ATB test as approved by the Secretary, and be enrolled in an eligible career pathway program pursuant to section 484(d)(1) of the Higher Education Act of 1965, as amended (HEA).

Students who first enrolled in any title IV eligible postsecondary program prior to July 1, 2012 may establish eligibility for title IV, program assistance using any of the following ATB alternatives—

- Passing an independently administered ATB test approved by the Secretary;
- Completing at least six credit hours, or the equivalent coursework (225 clock hours), that are applicable toward a degree or certificate offered by the postsecondary institution; or
- Completing a State process approved by the Secretary.

A student who does not have a high school diploma or its recognized equivalent, whose native language is not English and is not fluent in English, and who is enrolled in a program that is taught in the student's native language, must take an approved test developed in the student's native language pursuant to 34 CFR 668.153(a)(1).

A student who does not have a high school diploma or its recognized equivalent, whose native language is not English and is not fluent in English, and who is enrolled in a program that is taught in English, must take an ATB test designed to measure the English language competence of a non-native speaker. Students who are enrolled in such a program that has an ''English as a Second Language'' (ESL) component and who are enrolled in the ESL component, must take an approved ATB test specifically for a student whose native language is not English and who is not fluent in English. Students who are enrolled in an ESL program only also must take an approved ATB test specifically for a student whose native language is not English and who is not fluent in English, pursuant to 34 CFR 668.153(a)(2).

A student who does not have a high school diploma or its recognized equivalent, and whose native language is not English and is not fluent in English, who is enrolled in a program that is taught in English without an ESL component, or the student does not enroll in the ESL component of the program, must take an ATB test in English that assesses secondary school verbal and quantitative skills, pursuant to 34 CFR 668.153(a)(3).

List of approved tests and passing scores: The Secretary lists below all approved ATB tests and their passing scores. The list is updated to reflect revisions to the list of approved ATB tests and passing scores that was published in the **Federal Register** on May 19, 2006 (97 FR 29135) and updates to the list that were made through an Electronic Announcement dated June 24, 2015, at *https://ifap.ed.gov/electronic-announcements/06-24-2015-general-subject-approved-ability-benefit-atb-tests.*

ATB test	Passing scores	Test publisher contact information
Wonderlic Basic Skills Test (WBST) Verbal Forms VS–1 & VS–2, Quantitative Forms QS–1 & QS–2 Paper and pencil versions and online versions. Effective Date: July 1, 2015.	Verbal (200) Quantitative (210)	Wonderlic, Inc., 400 Lakeview Parkway, Suite 200, Vernon Hills, IL 60061. Contact: Chris Young. Telephone: (847) 247–2544. Fax: (847) 680–9492.
Spanish Wonderlic Basic Skills Test (Spanish WBST) Verbal Forms VS–1 & VS–2, Quantitative Forms QS–1 & QS–2 Paper and pencil versions and online versions. Effective Date: July 1, 2015.	Verbal (200), Quantitative (200).	
Combined English Language Skills Assessment (CELSA),* Forms 1 and 2 Effective Date: November 1, 2002.	CELSA Form 1 (97), CELSA Form 2 (97)	Association of Classroom Teacher Testers (ACCT), 1187 Coast Village Road, Suite 1, #378, Montecito, CA 93108. Contact: Pablo Buckelew. Telephone: (805) 965–5704. Fax: (805) 965–5807.
**ACCUPLACER Computer-adaptive tests and COMPANION ACCUPLACER Forms J and K: Reading Test, Writing Test, and Arithmetic Test.	Reading Test (233),** Writing Test (235),** Arithmetic Test (230) **.	The College Board, 250 Vesey Street, New York, NY 10281. Contact: ACCUPLACER Program. Telephone: (800) 607–5223. Fax: (212) 253–4061.
** Texas Success Initiative (TSI) Assessment—Computer-adaptive tests and COMPANION TSI Forms T and V: Reading Placement Test, Writing Placement Test, Mathematics Placement Test.	Reading Placement Test (336), Writing Placement Test (345), Mathematics Placement Test (326).	

* **Note:** As provided in 34 CFR 668.153(a)(2), the CELSA test is approved as the additional ATB English language proficiency test that must be taken by students whose native language is not English and who are not fluent in English if the academic program includes an ESL component.

** The ACCUPLACER test has been redesigned since it was listed as an approved test in the 2006 notice. TSI is a new addition to the list of approved ATB tests. These tests are provisionally approved. To move from provisional approval to full approval the test publisher must submit additional information as noted in the test agreement signed by the test publisher and the Department, no later than two years from the effective date of the agreement 6/26/2020. In the event the Department denies full approval, we will provide notice of this through publication in the **Federal Register**, pursuant to 34 CFR 668.150(c)(3).

List of ATB tests that are no longer approved: The following six tests appeared on the list of approved tests published in the 2006 **Federal Register** notice, but are not on the current list of tests that may be used for the purpose of determining a student's eligibility for title IV, program assistance. Please note the effective dates for each test.

1. *Test:* The ACT Career Programs Assessment test (CPAt)—Forms B and C.

Effective Dates: November 1, 2002 through June 30, 2015.

Passing Scores: Language Usage (42), Reading (43), and Numerical (41).

Publisher: ACT, Inc., 500 ACT Drive, P.O. Box 168, Iowa City, IA 52243–0168.

Contact: Joanna Higgins-Freese; Telephone: (319) 337–1618.

2. *Test:* The ACT WorkKeys test—Reading for Information—Forms A01AA, A02AA, C01AA, & D10AA; Applied Mathematic—Forms A01BB, A02BB, C01BB, & D01BB.

Effective Dates: May 19, 2006 through June 30, 2015.

Passing Scores: Reading for Information Forms A01AA (76), A02AA (75), C01AA (77), & D10AA (77); Applied Mathematics Forms A01BB (73), A02BB (74), C01BB (73), & D01BB (73).

Publisher: ACT, Inc., 500 ACT Drive, P.O. Box 168, Iowa City, IA 52243–0168.

Contact: Joanna Higgins-Freese; Telephone: (319) 337–1618.

3. *Test:* The College Board DTLS and DTMS Forms M–K–3KDT and M–K–3LDT tests.

Effective Dates: November 1, 2002 through April 27, 2007.

Passing Scores: Reading Comprehension (108), Sentence Structure (9), Conventions of Written English (309), and Arithmetic (506).

Publisher: The College Board, 250 Vesey Street, New York, New York 10281.

Contact: ACCUPLACER Program; Telephone: (800) 607–5223, Fax (212) 253–4061.

4. *Test:* ASSET: Basic Skills Test (Reading, Writing, and Numerical)—Forms B2, C2, D2, and E2.

Effective Dates: November 1, 2002 through October 31, 2015.

Passing Scores: Reading (35), Writing (35), and Numerical (33).

Publisher: ACT, Inc., 500 ACT Drive, P.O. Box 168, Iowa City, IA 52243–0168.

Contact: Joanna Higgins-Freese; Telephone: (319)–337–1618.

5. *Test:* COMPASS Subtests—Prealgebra/Numerical Skills.

Passing Scores: Prealgebra/Numerical (25), Reading (62), and Writing (32).

Effective Dates: November 1, 2002 through October 31, 2015.

Publisher: ACT, Inc., 500 ACT Drive, P.O. Box 168, Iowa City, IA 52243–0168.

Contact: Joanna Higgins-Freese; Telephone: (319) 337–1618.

6. *Test:* COMPASS ESL.

Passing Scores: Grammar/Usage (64), Reading (70), and Listening (70).

Effective Dates: May 19, 2006 through October 31, 2015.

Publisher: ACT, Inc., 500 ACT Drive, P.O. Box 168, Iowa City, IA 52243–0168.

Contact: Joanna Higgins-Freese; Telephone: (319) 337–1618.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1091(d).

Robert L. King,

Assistant Secretary for the Office of Postsecondary Education.

[FR Doc. 2020–24795 Filed 11–6–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Fund for the Improvement of Postsecondary Education—Career and Educational Pathways Exploration System Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2020 for the Fund for the Improvement of Postsecondary Education (FIPSE) Career and Educational Pathways Exploration System (Career Pathways) Program, Assistance Listing Number 84.116C. This notice relates to the approved information collection under OMB control number 1894–0006.

DATES: Applications Available: November 9, 2020. Deadline for Transmittal of Applications: December 9, 2020.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Sharon Easterling, U.S. Department of Education, 400 Maryland Avenue SW, Room 278–14, Washington, DC 20202–4260. Telephone: (202) 453–7425. Email: *Sharon.Easterling@ed.gov,* or Carmen Gordon, U.S. Department of Education, 400 Maryland Avenue SW, Room 278–42, Washington, DC 20202–4260. Telephone (202) 453–7311. Email: *Carmen.Gordon@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Career Pathways Program funded through FIPSE is to develop technology-based or technology-enabled career exploration systems that enable high school students to identify and explore career opportunities that align with their interests, ambitions, and aptitudes; learn from individuals who work in those fields about the nature of their work and opportunities available in their fields; and identify education and training options—including non-college programs such as work-based learning opportunities, military training, apprenticeships, and employer-sponsored training—that enable entry into or advancement in those careers. Career and education pathways exploration systems must include, for featured occupations, information about employment outlook and likely entry and mid-career earnings in featured fields, and they must enable students to use built-in financial analysis tools to explore the economic impact of their career, education, and training choices.

Background: In FY 2020, Congress appropriated $24.5 million to FIPSE, including $10 million designated to the Career Pathways Program, to support the development of Career and Education Pathways Exploration Systems that will increase student awareness of the many career opportunities available to them and knowledge among students, educators, parents, and counselors about the many education and training pathways that provide entry to and advancement in those careers. These grants are intended to support the creation of scalable career exploration and guidance systems that help students identify their career interests; explore potential occupations that align with those interests; interact with individuals who work in particular jobs of interest to them, or with artificial intelligence or other interactive technologies in the fields of interest; consider the various education and training options (including non-college options, such as work-based learning, apprenticeships, employer-sponsored training, and military service) that enable entrance to and advancement in those occupations; and identify the attitudes, skills, and aptitudes necessary to be successful in those fields.

Through this grant competition, we invite non-profit organizations with expertise in workforce development or career counseling, alone or in partnership with institutions of higher education (IHEs) or other non-profit agencies/organizations, trade associations, employers, States, and labor unions to develop, adapt, or expand career exploration and guidance systems that will enable students (and their parents) to engage in career exploration and education/training

planning. These systems must be technology based so that they can be deployed at scale, and they must include financial analysis tools that allow students to compare the direct and opportunity costs (including student loan interest) of the educational pathways they are considering as well as earnings potential among occupations of interest.

These exploration and guidance systems must feature the full range of education and training pathways, including short-term programs (less than 600 hours), apprenticeships, employer-sponsored training, military training opportunities, and more traditional college pathways.

Priority: This notice contains one absolute priority. We are establishing this priority for the FY 2020 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA), 20 U.S.C. 1232 (d)(1).

Absolute Priority: Under 34 CFR 75.105(c)(3), we consider only applications that meet this absolute priority.

Providing Career and Education Pathways Exploration Systems.

To meet this priority, applicants must submit—

(a) A plan to create or expand a sustainable technology-based or technology-enabled career and education pathways exploration system that accomplishes all of the following objectives:

(1) Enabling high school students to identify and learn about career opportunities based on their personal interests, aptitudes, and career goals;

(2) Enabling high school students to identify, consider, and compare the possible education and training pathways that lead to career entry and advancement in their fields of interest;

(3) Engaging individuals who work in featured occupations, or using other interactive bot technologies simulating interaction with an individual, to provide information to students about their experience working in the field, the aptitudes and attitudes that are necessary for success, and the challenges and opportunities typical for those who work in the field; and

(4) Enabling students to use embedded financial tools to compare the cost and benefits of the career options and educational pathways they are considering, including the long-term impact of taking student loans on their financial security, including likely entry and mid-career earnings in featured fields.

(b) An evaluation plan to assess the effectiveness of the system in assisting students in identifying their career goals, identifying potential education pathways to achieve that goal, and comparing the costs and benefits of each pathway.

(c) A logic model for developing and implementing the project.

Program Requirements: We are establishing the program requirements for the FY 2020 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition in accordance with section 437(d)(1) of GEPA.

The program requirements are:

Independent Evaluation.

A grantee must conduct an independent evaluation of the activities carried out under the grant and submit to the Department an annual report that includes—

(a) A description of how the grant funds were used;

(b) The performance of the project with respect to, at a minimum, the performance measures described in the approved application; and

(c) A quantitative analysis of the effectiveness of the project.

Use of Funds.

A grantee must use the funds awarded for the following activities:

(a) Development of a technology-based or technology-enabled career exploration and pathways system that enables students to identify career options and possible education and training pathways based on their interests, aptitudes, and goals.

(b) Identifying and recruiting individuals who work in featured occupations to participate in content development for the system and providing career information to students.

(c) Providing training to high school guidance counselors and teachers on proper use of the system to help students explore career opportunities and educational pathways.

(d) Disseminating information about the system to high schools, workforce development boards, training providers, IHEs, and other entities.

Definitions:

The definition of Institution of Higher Education is from section 101 of the Higher Education Act of 1965, as amended (HEA). The definitions of Baseline, Logic Model, Performance Measure, Performance Target, Project Component, and Relevant Outcome are from 34 CFR 77.1. We are establishing the definitions of Independent Evaluation, Parent, and Work-Based Learning for this competition in accordance with section 437(d)(1) of GEPA.

Baseline means the starting point from which performance is measured and targets are set.

Independent Evaluation means an evaluation of a Project Component that is designed and carried out independently of, but in coordination with, the entities that develop or implement the Project Component.

Institution of Higher Education (IHE) means—

(a) An educational institution in any State that—

(1) Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, or persons who meet the requirements of section 484(d)(3) of the HEA;

(2) Is legally authorized within such State to provide a program of education beyond secondary education;

(3) Provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary;

(4) Is a public or other nonprofit institution; and

(5) Is accredited by a nationally recognized accrediting agency or association or, if not so accredited, is an institution that has been granted pre-accreditation status by such an agency or association that has been recognized by the Secretary of Education for the granting of pre-accreditation status, and the Secretary of Education has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

(b) The term also includes:

(1) Any school that provides not less than a 1-year program of training to prepare students for gainful employment in a recognized occupation and that meets the provisions of paragraphs (1), (2), (4), and (5) of paragraph (a) of this definition; and

(2) A public or nonprofit private educational institution in any State that, in lieu of the requirement in paragraph (a)(1) of this definition, admits as regular students individuals—

(i) Who are beyond the age of compulsory school attendance in the State in which the institution is located; or

(ii) Who will be dually or concurrently enrolled in the institution and a secondary school.

Logic Model (also referred to as a theory of action) means a framework that identifies key Project Components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the Relevant Outcomes) and describes the theoretical and operational relationships among the key Project Components and Relevant Outcomes.

Parent means natural, adoptive, and foster parents, guardians, and individuals acting in the role of parent.

Performance Measure means any quantitative indicator, statistic, or metric used to gauge program or project performance.

Performance Target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project.

Project Component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Relevant Outcome means the student outcome(s) or other outcome(s) the key Project Component is designed to improve, consistent with the specific goals of the program.

Work-Based Learning means sustained interactions with industry or community professionals in real workplace settings, to the extent practicable, or simulated environments at an educational institution that foster in-depth, firsthand engagement with the tasks required of a given career field, that are aligned to curriculum and instruction.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed priorities, requirements, and definitions. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program under a new or substantially revised authority and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priorities, requirements, and definitions under section 437(d)(1) of GEPA. These priorities, requirements, and definitions will apply to the FY 2020 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: 20 U.S.C. 1138–1138d, the explanatory statement accompanying H.R. 1865 (Pub. L. 116–94), Congressional Record, daily edition, Dec. 17, 2019, at H11083.

Note: Projects must be awarded and operated in a manner consistent with the nondiscrimination requirements contained in the U.S. Constitution and the Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The regulations in 34 CFR 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $9,900,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Range of Awards: $4,400,000–9,000,000 for the 36-month project period.

Estimated Average Size of Awards: $4,950,000 for the 36-month project period.

Estimated Number of Awards: 1–2.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

III. Eligibility Information

1. *Eligible Applicants:* Public and private nonprofit institutions and agencies (other than IHEs) with expertise in workforce development or career counseling, alone or in partnership with IHEs or other public and private nonprofit institutions and agencies (such as State workforce development boards, employers, trade associations, or labor unions).

Note: Only public and private nonprofit institutions and agencies may be the fiscal agent in this competition. IHEs may be included as a partner in a grant in which public and private nonprofit institutions and agencies are the fiscal agent as a group application consistent with 34 CFR 75.127–75.129.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Supplement-Not-Supplant:* This competition involves supplement-not-supplant funding requirements.

c. *Indirect Cost Rate Information:* We are establishing a training indirect cost rate for this program. This limits indirect cost reimbursement to an entity's actual indirect costs, as determined in its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. For more information regarding training indirect cost rates, see 34 CFR 75.562. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

d. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200, subpart E, of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs,

published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make awards by December 31, 2020.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 25 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger, and no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

V. Application Review Information

1. *Selection Criteria:* The following selection criteria for this competition are from 34 CFR 75.210. Applicants should address each of the following selection criteria. The selection criteria are worth a total of 100 points; the maximum score for each criterion is noted in parentheses.

(a) *Significance.* (Maximum 20 points) The Secretary considers the significance of the proposed project. In determining the significance of the proposed project, the Secretary considers the following factors:

(1) The extent to which the proposed project is likely to build local capacity to provide, improve, or expand services that address the needs of the target population. (10 points)

(2) The potential replicability of the proposed project or strategies, including, as appropriate, the potential for implementation in a variety of settings. (10 points)

(b) *Quality of the project design.* (Maximum 25 points) The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers:

(1) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable. (5 points)

(2) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs. (5 points)

(3) The extent to which the design for implementing and evaluating the proposed project will result in information to guide possible replication of project activities or strategies, including information about the effectiveness of the approach or strategies employed by the project. (5 points)

(4) The extent to which the proposed project represents an exceptional approach to the priority or priorities established for the competition. (10 points)

(c) *Quality of project services.* (Maximum 10 points) The Secretary considers the quality of the services to be provided by the proposed project.

(1) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (3 points)

(2) In addition, the Secretary considers:

(i) The extent to which the services to be provided by the proposed project are appropriate to the needs of the intended recipients or beneficiaries of those services. (3 points)

(ii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice. (4 points)

(d) *Quality of project personnel.* (Maximum 10 points) The Secretary considers the quality of the personnel who will carry out the proposed project.

(1) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. (3 points)

(2) In addition, the Secretary considers:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator. (4 points)

(ii) The qualifications, including relevant training and experience, of key project personnel. (3 points)

(e) *Adequacy of resources.* (Maximum 5 points) The Secretary considers the adequacy of resources for the proposed project. In determining the adequacy of resources for the proposed project, the Secretary considers:

(1) The extent to which the budget is adequate to support the proposed project. (3 points)

(2) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project. (2 points)

(f) *Quality of the management plan.* (Maximum 15 points) The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks. (5 points)

(2) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project. (5 points)

(3) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project. (5 points)

(g) *Quality of the project evaluation.* (Maximum 15 points) The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers:

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project. (10 points)

(2) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible. (5 points)

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:*

(a) For the purposes of the Government Performance and Results Act of 1993 (GPRA) and reporting under 34 CFR 75.110, the Secretary establishes the following indicators to measure progress towards achieving the purposes of the program: The percentage of grantees producing independent evaluations that demonstrate improved effectiveness and alignment of career guidance and exploration systems with improved student outcomes. In addition, applicants must propose project-specific performance measures and performance targets consistent with the objectives of the proposed project.

Applications must provide the following information as directed under 34 CFR 75.110(b) and (c):

(b) Project-specific performance measures. How each proposed performance measure would accurately measure the performance of the project and how the proposed performance measures would be consistent with the performance measures established for the program funding the competition.

(c) Baseline data.

(1) Why each proposed baseline is valid; or

(2) If the applicant has determined that there are no established baseline data for a particular performance measure, an explanation of why there is no established baseline and of how and when, during the project period, the applicant would establish a valid baseline for the performance measure.

(d) Performance targets. Why each proposed performance target is ambitious yet achievable compared to the baseline for the performance measure and when, during the project period, the applicant would meet the performance target(s).

(e) Data collection and reporting.

(1) The data collection and reporting methods the applicant would use and

why those methods are likely to yield reliable, valid, and meaningful performance data; and

(2) The applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

All grantees must submit an annual performance report with information that is responsive to these performance measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc), to the extent reasonably practicable.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Robert L. King,

Assistant Secretary for the Office of Postsecondary Education.

[FR Doc. 2020–24814 Filed 11–6–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0140]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Gaining Early Awareness and Readiness for Undergraduate Programs (GEAR UP) Final Performance Report

AGENCY: Office of Postsecondary Education, Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement without change of a previously approved collection.

DATES: Interested persons are invited to submit comments on or before December 9, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Ben Witthoefft, 202–453–7576.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Gaining Early Awareness and Readiness for Undergraduate Programs (GEAR UP) Final Performance Report.

OMB Control Number: 1840–0782.

Type of Review: Reinstatement without change of a previously approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 165.

Total Estimated Number of Annual Burden Hours: 7,425.

Abstract: The purpose of this information collection is to determine whether recipients of Gaining Early Awareness and Readiness for Undergraduate Programs (GEAR UP) have made substantial progress towards meeting the objectives of their respective projects, as outlined in their grant applications and/or subsequent work plans. In addition, the final report will enable the Department to evaluate each grant project's fiscal operations for the entire grant performance period, and compare total expenditures relative to federal funds awarded, and actual cost-share/matching relative to the total amount in the approved grant application. This report is a means for grantees to share the overall experience of their projects and document achievements and concerns, and describe effects of their projects on participants being served; project barriers and major accomplishments; and evidence of sustainability. The report will be GEAR UP's primary method to collect/analyze data on students' high school graduation and immediate college enrollment rates.

Dated: November 4, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–24798 Filed 11–6–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0171]

Agency Information Collection Activities; Comment Request; National Survey of Charter School Facilities

AGENCY: Office of Innovation and Improvement, Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before January 8, 2021.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0171. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Nicoisa Jones, (202) 453–6695.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: National Survey of Charter School Facilities.

OMB Control Number: 1855–0024.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 700.

Total Estimated Number of Annual Burden Hours: 397.

Abstract: This is a revision to the national survey on charter school facilities that is designed to inform the public of the conditions and operations of buildings used by charter schools. The survey questionnaire includes 45 questions. Depending on the facility status of schools, respondents will follow skip patterns to answer questions that are only relevant to their schools. A pilot test shows that the questionnaire takes approximately 34 minutes to complete. National Charter School Resource Center (NCSRC) will administer in fall 2021 via an online survey platform. Responses to the survey questions will inform the public of the physical conditions of buildings charter schools use as well as resources and challenges for charter schools to access and maintain facilities.

The survey follows a stratified systematic design to draw a sample of 700 charter schools nationwide. NCSRC will coordinate with Charter School Organizations (CSOs) and local entities to recruit schools and maximize the response rate of the survey. NCSRC staff will clean and analyze the survey data using statistical analytic and reporting techniques appropriate to the data collected.

Dated: November 4, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–24854 Filed 11–6–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Orders Issued Under Section 3 of the Natural Gas Act During September 2020

	FE docket Nos.
EVERSOURCE GAS COMPANY OF MASSACHUSETTS	20–97–NG
TRANSCANADA PIPELINES LIMITED	20–81–NG
CIMA ENERGY, LP	20–89–NG
VISTA ENERGY MARKETING, L.P	20–84–NG
MERRILL LYNCH COMMODITIES, INC	20–86–NG
ATLANTIC POWER ENERGY SERVICES (U.S.) LLC	20–85–NG
ALLIANCE PIPELINE L.P	20–87–NG
ENHANCED ENERGY SERVICES OF AMERICA, LLC	20–88–NG
CLEANCOR ENERGY SOLUTIONS LLC	20–89–LNG
STABILIS GDS, INC	20–83–LNG
BOISE WHITE PAPER L.L.C	20–90–NG
ALBERTA NORTHEAST GAS LIMITED	20–92–NG
PETROCHINA INTERNATIONAL (AMERICA), INC	20–91–NG

	FE docket Nos.
NORTHEAST GAS MARKETS, LLC	20–93–NG
DTE GAS COMPANY	20–94–NG
SIERRA PRODUCTION COMPANY	20–96–NG
UNITED STATES GYPSUM COMPANY	20–100–NG
ABAG PUBLICLY OWNED ENERGY RESOURCES	20–101–NG
PUGET SOUND ENERGY, INC	20–106–LNG
MIECO LLC	20–104–NG; 19–32–NG
NS POWER ENERGY MARKETING INC	20–105–NG
CENTRAL HUDSON GAS & ELECTRIC CORPORATION	20–108–NG
NORTHERN UTILITIES, INC	20–109–NG
YANKEE GAS SERVICES COMPANY	20–110–NG
LIBERTY UTILITIES (ENERGYNORTH NATURAL GAS) CORP. d/b/a LIBERTY UTILITIES	20–111–NG
SEQUENT ENERGY MANAGEMENT, L.P	20–119–NG
THE SOUTHERN CONNECTICUT GAS COMPANY	20–112–NG
SABINE PASS LIQUEFACTION, LLC	20–114–LNG
CONNECTICUT NATURAL GAS CORPORATION	20–113–NG
ENERGY PLUS NATURAL GAS LLC	20–121–NG
NATURGY APROVISIONAMIENTOS S.A	20–116–LNG

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during September 2020, it issued orders granting authority to import and export natural gas, to import and export liquefied natural gas (LNG), and vacating prior authorization. These orders are summarized in the attached appendix and may be found on the FE website at *https://www.energy.gov/fe/listing-doefe-authorizationsorders-issued-2020*. They are also available for inspection and copying in the U.S. Department of Energy (FE–34), Division of Natural Gas Regulation, Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9387. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Signed in Washington, DC, on November 4, 2020.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Oil and Natural Gas.

Appendix

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

4572	09/01/20	20–97–NG	Eversource Gas Company of Massachusetts.	Order 4572 granting blanket authority to import/export natural gas from/to Canada.
4573	09/01/20	20–81–NG	TransCanada PipeLines Limited	Order 4573 granting blanket authority to import/export natural gas from/to Canada.
4574	09/01/20	20–98–NG	CIMA Energy, LP	Order 4574 granting blanket authority to import/export natural gas from/to Canada/Mexico.
4575	09/01/20	20–84–NG	Vista Energy Marketing, L.P	Order 4575 granting blanket authority to import natural gas from Canada.
4576	09/01/20	20–86–NG	Merrill Lynch Commodities, Inc	Order 4576 granting blanket authority to import/export natural gas from/to Canada/Mexico.
4577	09/04/20	20–85–NG	Atlantic Power Energy Services (US) LLC.	Order 4577 granting blanket authority to import/export natural gas from/to Canada.
4578	09/04/20	20–87–NG	Alliance Pipeline L.P	Order 4578 granting blanket authority to import natural gas from Canada.
4579	09/04/20	20–88–NG	Enhanced Energy Services of America, LLC.	Order 4579 granting blanket authority to import natural gas from Canada.
4580	09/04/20	20–89–LNG	CLEANCOR Energy Solutions LLC	Order 4580 granting blanket authority to export LNG to Canada/Mexico by vessel/truck.
4581	09/11/20	20–83–LNG	Stabilis GDS, Inc	Order 4581 granting blanket authority to import/export LNG from/to Canada/Mexico by truck.
4582	09/04/20	20–90–NG	Boise White Paper L.L.C	Order 4582 granting blanket authority to import natural gas from Canada.
4583	09/04/20	20–92–NG	Alberta Northeast Gas Limited	Order 4583 granting blanket authority to import/export natural gas from/to Canada.
4584	09/04/20	20–91–NG	PetroChina International (America), Inc.	Order 4584 granting blanket authority to import/export natural gas from/to Canada/Mexico, to import LNG from various international sources by vessel, and to export LNG to Canada/Mexico by vessel.
4585	09/04/20	20–93–NG	Northeast Gas Markets, LLC	Order 4585 granting blanket authority to import/export natural gas from/to Canada.
4586	09/04/20	20–94–NG	DTE Gas Company	Order 4586 granting blanket authority to import/export natural gas from/to Canada.
4587	09/04/20	20–96–NG	Sierra Production Company	Order 4587 granting blanket authority to import natural gas from Canada.
4589	09/04/20	20–100–NG	United States Gypsum Company	Order 4589 granting blanket authority to import natural gas from Canada.

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS—Continued

4590	09/04/20	20–101–NG	ABAG Publicly Owned Energy Resources.	Order 4590 granting blanket authority to import natural gas from Canada.
4591	09/04/20	20–106–LNG	Puget Sound Energy, Inc	Order 4591 granting blanket authority to import LNG from Canada by truck.
4592; 4361–A	09/11/20	20–104–NG; 19–32–NG	Mieco LLC	Order 4592 granting blanket authority to import/export natural gas from/to Canada, and vacating prior authority (Order 4361).
4593	09/11/20	20–105–NG	NS Power Energy Marketing Inc	Order 4593 granting blanket authority to import/export natural gas from/to Canada.
4594	09/23/20	20–108–NG	Central Hudson Gas & Electric Corporation.	Order 4594 granting blanket authority to import/export natural gas from/to Canada.
4595	09/23/20	20–109–NG	Northern Utilities, Inc	Order 4595 granting blanket authority to import/export natural gas from/to Canada.
4596	09/24/20	20–110–NG	Yankee Gas Services Company	Order 4596 granting blanket authority to import/export natural gas from/to Canada.
4597	09/23/20	20–111–NG	Liberty Utilities (EnergyNorth Natural Gas) Corp. d/b/a Liberty Utilities.	Order 4597 granting blanket authority to import/export natural gas from/to Canada.
4598	09/23/20	20–119–NG	Sequent Energy Management, L.P	Order 4598 granting blanket authority to import/export natural gas from/to Mexico.
4599	09/23/20	20–112–NG	The Southern Connecticut Gas Company.	Order 4599 granting blanket authority to import/export natural gas from/to Canada.
4600	09/23/20	20–114–LNG	Sabine Pass Liquefaction, LLC	Order 4600 granting blanket authority to import LNG from various international sources by vessel.
4601	09/23/20	20–113–NG	Connecticut Natural Gas Corporation	Order 4601 granting blanket authority to import/export natural gas from/to Canada.
4602	09/23/20	20–121–NG	Energy Plus Natural Gas LLC	Order 4602 granting blanket authority to import/export natural gas from/to Canada.
4603	09/24/20	20–116–LNG	Naturgy Aprovisionamientos S.A	Order 4603 granting blanket authority to import LNG from various international sources by vessel.

[FR Doc. 2020–24820 Filed 11–6–20; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD21–5–000]

Impact of Electric Vehicles on the Transmission System and Wholesale Electricity Markets; Notice of Roundtable Discussion

Take notice that the Chairman of the Federal Energy Regulatory Commission (FERC or Commission) will convene a roundtable to discuss the increased deployment of electric vehicles (EVs) and EV charging infrastructure nationwide and their impact on and value to the FERC-jurisdictional transmission system and wholesale electricity markets. The purpose of this roundtable is to begin a conversation on the state of EV deployment and identify some of the questions both the Commission and the energy industry will need to address as deployment of EVs increases. The Chairman will lead the roundtable discussion, and Commissioners may participate.

The roundtable will be held on December 3, 2020 from approximately 1:00 p.m. to 3:00 p.m. Eastern Time. The roundtable will be held electronically over WebEx and broadcast on the Commission's website. The roundtable will be open for the public to observe, and there is no fee for attendance. A supplemental notice will be issued prior to the roundtable with further details regarding the agenda and organization, and any changes to the date and/or time of the roundtable. Information on this roundtable will also be posted on the Calendar of Events on the Commission's website, *www.ferc.gov,* prior to the event. The roundtable event will not be transcribed.

For more information about this roundtable, please contact Michael Hill, 202–502–8703, *michael.hill@ferc.gov* for technical questions or Sarah McKinley, 202–502–8368, *sarah.mckinley@ferc.gov* for logistical issues.

Dated: October 30, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–24856 Filed 11–6–20; 8:45 am]
BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

[MB Docket No. 11–43; DA 20–1301; FRS ID 17222]

Audio Description: Preliminary Nonbroadcast Network Rankings

AGENCY: Federal Communications Commission

ACTION: Notice.

SUMMARY: FCC announces the top national nonbroadcast network rankings from the 2019–2020 ratings year, and gives networks the opportunity to seek exemption from the July 1, 2021 update to the Commission's audio description requirements.

DATES: Exemption requests are due December 9, 2020.

ADDRESSES: Filings should be submitted electronically in MB Docket No. 11–43 by accessing the Commission's Electronic Comment Filing System (ECFS) at *https://www.fcc.gov/ecfs/.* Filers should follow the instructions provided on the website for submitting filings.

FOR FURTHER INFORMATION CONTACT: For further information, contact Michael Scurato (202–418–2083; *Michael.Scurato@fcc.gov*).

SUPPLEMENTARY INFORMATION: This is a summary of the Media Bureau's Public Notice, DA 20–1301, released on November 2, 2020. The full text of this public notice will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat via ECFS. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *fcc504@fcc.gov* or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Audio description makes video programming accessible to individuals who are blind or visually impaired through ''[t]he insertion of audio narrated descriptions of a television program's key visual elements into natural pauses between the program's dialogue.'' The Commission's audio description rules require multichannel video programming distributor (MVPD) systems that serve 50,000 or more subscribers to provide 87.5 hours of audio description per calendar quarter on channels carrying each of the top five national nonbroadcast networks. The top five national nonbroadcast networks are defined by an average of the national audience share during prime time among nonbroadcast networks that reach 50 percent or more of MVPD households and have at least 50 hours per quarter of prime time programming that is not live or near-live or otherwise exempt under the audio description rules. The nonbroadcast networks currently subject to the audio description requirements are USA, HGTV, TBS, Discovery, and History.

In accordance with the Commission's rules, the list of top five nonbroadcast networks is updated at three year intervals to account for changes in ratings, and the third triennial update will occur on July 1, 2021, based on the 2019 to 2020 ratings year. According to data provided by the Nielsen Company, the top ten nonbroadcast networks for the 2019 to 2020 ratings year are: Fox News, MSNBC, CNN, ESPN, TLC, HGTV, Hallmark, History, TBS, and Discovery.

If a program network believes it should be excluded from the list of top five networks covered by the audio description requirements because it does not air at least 50 hours per quarter of prime time programming that is not live or near-live or is otherwise exempt, it must seek an exemption no later than 30 days after publication of this Public Notice in the **Federal Register**. The Media Bureau will promptly evaluate requests for exemption and will provide notice of any resulting revisions to the list.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

[FR Doc. 2020–24815 Filed 11–6–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FRS 17207]

Privacy Act of 1974; System of Records

AGENCY: Federal Communications Commission.

ACTION: Notice of a modified system of records.

SUMMARY: The Federal Communications Commission (FCC, Commission, or Agency) has modified an existing system of records, FCC/OMD–3, Federal Advisory Committee Act (FACA) Membership Files, subject to the Privacy Act of 1974, as amended. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of records maintained by the Agency. The FCC uses this information to manage its Federal Advisory Committees (''advisory committees'' or ''committees''), which provide expertise and advice on a broad range of issues affecting policies and programs.

DATES: This action will become effective on November 9, 2020. Written comments on the system's routine uses are due by December 9, 2020. The routine uses in this action will become effective on December 9, 2020, unless written comments are received that require a contrary determination.

ADDRESSES: Send comments to Privacy Team, Federal Communications Commission, 45 L Street NE, Washington, DC 20554, or *Privacy@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Margaret Drake, Privacy Team, Federal Communications Commission, 45 L Street NE, Washington, DC 20554, 202–418–1707, or *Privacy@fcc.gov* (and to obtain a copy of the Narrative Statement and the Supplementary Documentation, which includes details of the modifications to this system of records).

SUPPLEMENTARY INFORMATION: FCC/OMD–3 helps the FCC manage Federal Advisory Committees, which provide expertise and advice on a broad range of issues affecting policies and programs. This notice serves to modify FCC/OMD–3 as a result of various necessary changes and updates, which include format changes required by OMB Circular A–108 since its previous publication. The substantive changes and modification to the previously published version of FCC/OMD–3 system of records include:

1. Updating the Security Classification to be consistent with FCC policies and Executive Order 13556.
2. Updating/revising the language in the Categories of Individuals to include applicants/nominees for membership to FCC Federal Advisory Committees.
3. Updating/revising the Categories of Records to include information collected from applicants/nominees for membership to FCC Federal Advisory Committees.
4. Updating/revising the Records Source Categories to include applicants/nominees for membership to FCC Federal Advisory Committees.
5. Updating and/or revising language in seven Routine Uses: (1) Committee Communication and Reporting; (2) Public Access; (3) Adjudication and Litigation, (4) Law Enforcement and Investigation, (5) Congressional Inquiries, (6) Government-wide Program Management and Oversight, and (7) Breach Notification.
6. Adding two new Routine Uses: (8) Assistance to Federal Agencies and Entities, to allow the FCC to provide assistance to other Federal agencies in their data breach situations, as required by OMB Memorandum M–17–12; and (9) Contract Services, Grants, or Cooperative Agreements, to allow contractors performing or working on a contract for the Federal Government access to information in this system.
7. Adding two new sections: Reporting to a Consumer Reporting Agency, to address valid and overdue debts owed by individuals to the FCC under the Debt Collection Act, as recommended by OMB; and a History section referencing the previous publication of this SORN in the **Federal Register**, as required by OMB Circular A–108.
8. Updating the Policies and Practices for Retention and Disposal of Records in this system to state that the records in this system are covered by the National Archives and Records Administration's (NARA) General Records Schedule (GRS) DAA–GRS–2015–0001 (GRS 6.2) Federal Advisory Committee Records.

The system of records is also updated to reflect various administrative changes related to the policy and practices for storage and retrieval of the information; administrative, technical, and physical safeguards; and updated notification, records access, and procedures to contest records.

SYSTEM NAME AND NUMBER: FCC/OMD–3, FEDERAL ADVISORY COMMITTEE ACT (FACA) MEMBERSHIP FILES.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

1. General Files (stored electronically): Associate Managing Director—Performance Evaluation and Records Management (PERM), Office of Managing Director (OMD), Federal Communications Commission (FCC), Washington, DC 20554; (202) 418–7044.

2. Financial Disclosure Files (*i.e.,* OGE Form 450 and FCC Form A54A): Office of General Counsel (OGC), Federal Communications Commission (FCC), Washington, DC 20554; (202) 418–1720.

3. Committee-Specific Files: Information concerning the FCC's current FACA Committees may be found at: *https://fcc.gov/about-fcc/advisory-committees-fcc.*[1]

SYSTEM MANAGER(S) AND ADDRESS:

Associate Managing Director, Performance Evaluation and Records Management (PERM), Office of Managing Director (OMD), Federal Communications Commission (FCC), Washington, DC 20554.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix 2; 5 U.S.C. App. (''Ethics in Government Act''); and Executive Order (E.O.) 12674 (as modified by E.O. 12731).

PURPOSE(S) OF THE SYSTEM:

This system includes the personally identifiable information (PII) of applicants/nominees and members of the FCC's Federal Advisory Committee ACT (FACA) committees, including but not limited to, their contact data. The information in this system includes, but is not limited to, information that is used to:

1. Communicate effectively and promptly with the FCC's FACA committee applicants, members, individual participants, and administrative assistants;

2. Complete mandatory reports to Congress and the General Services Administration (GSA) about FACA advisory committee matters; and

3. Ensure compliance with all ethical and conflict-of-interest requirements concerning the applicants/nominees and members of the FCC's FACA advisory committees, including the requirements in OGE Form 450.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The categories of individuals in this system include, but are not limited to:

1. Applicants/Nominees to FACA committees sponsored or co-sponsored by FCC;

2. Members of FACA committees sponsored or co-sponsored by the FCC;

3. Individual participants in FACA working groups/subcommittees (who are not necessarily appointed members of the advisory committee); and

4. Administrative Assistant(s) or other similar contact(s) within the organization that an advisory committee member represents.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in this system include, but are not limited to:

1. FACA Committee Applicants/Nominees and Members:

Applicant/Nominee/Member's full name, home address(es), organization represented, home email address(es), home telephone and personal cellphone number(s), fax number(s), resume (*e.g.,* which includes, but is not limited to the full name, home address, home, cell, and other telephone numbers, home fax number(s), home email address(es), work experience, educational attainment, and references), nominee's qualifications statement, and/or letters of recommendation (*e.g.,* which includes, but is not limited to the reference's name, address, telephone numbers(s), email address(es), and personal evaluation/recommendation of their colleague's job performance, skills, abilities, and related information), Federal lobbyist status (yes/no), area(s) of expertise, and occupation (or title), and tribal, (non-English speaking) linguistic, disability, elderly, and related group affiliation(s), which, are kept with the applicant/nominee/member's respective advisory committee.

2. Individual participants in FACA working groups/subcommittees (who are not necessarily members of the advisory committee):

Participant's full name, home address(es), organization represented, home email address(es), home telephone and personal cellphone number(s), fax number(s), resume (*e.g.,* which includes, but is not limited to the full name, home address, home, cell, and other telephone numbers, home fax number(s), home email address(es), work experience, educational attainment, and references), nominee's qualifications statement, and/or letters of recommendation (*e.g.,* which includes, but is not limited to the reference's name, address, telephone numbers(s), email address(es), and personal evaluation/recommendation of their colleague's job performance, skills, abilities, and related information), Federal lobbyist status (yes/no), area(s) of expertise, and occupation (or title), and tribal, (non-English speaking) linguistic, disability, elderly, and related group affiliation(s), which, are kept with the participant's respective advisory committee.

3. Committee Members' assistants or organizational contacts:

Assistant/organizational contact's full name, home address(es), organization represented, home email address(es), home telephone and personal cellphone number(s), fax number(s), resume (*e.g.,* which includes, but is not limited to the full name, home address, home, cell, and other telephone numbers, home fax number(s), home email address(es), and related information), Federal lobbyist status (yes/no), area(s) of expertise, and occupation (or title), and tribal, (non-English speaking) linguistic, disability, elderly, and related group affiliation(s), which are kept with the respective advisory committee.

4. Originals or copies of the financial disclosure form, OGE Form 450,[2] and associated vetting documentation, which the FACA committee applicants/nominees and members may be required to file in accordance with the requirements of the Ethics in Government Act of 1978 and the Ethics Reform Act of 1989, as amended, and E.O. 12674, as modified.

RECORD SOURCE CATEGORIES:

The sources for the information in this system include, but are not limited to, the information that is supplied by individuals applying for membership to the FCC's FACA committees, members of the FCC's FACA committees, individual participants in the FCC's FACA committee working groups/subcommittees, and advisory committee members' administrative assistants or organizational contacts.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside the FCC as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows. In each of these cases, the FCC will determine whether disclosure of the records is compatible with the

[1] The list of FACAs covered by the system of records is subject to change, as reflected on the Commission's website.

[2] The PII contained in OGC Form 450 is covered by the Office of Government Ethics' government-wide system of records, OGE/GOVT–2, Executive Branch Confidential Financial Disclosure Report. *See* 84 FR 47301.

purpose(s) for which the records were collected:

1. Committee Communication and Reporting—Records in this system may be disclosed to the Chair (or Vice Chair) of the advisory committee for purposes of determining membership on appropriate subcommittees or assignment of tasks to achieve the committee's goals, and/or used to distribute information to the FACA committee members, their assistants, and other participants for the purposes of conducting meetings, general committee business, and/or preparing reports on the membership and work of the committee.

2. Public Access—The public can access information about the FCC's Federal Advisory Committee Act (FACA) committees at: *https://www.fcc.gov/about-fcc/advisory-committees-fcc,* as well as in the searchable database found on the General Services Administration's (GSA) website at *https://www.facadatabase.gov/FACA/FACAPublicPage.*

3. Adjudication and Litigation—To disclose information to the Department of Justice (DOJ), or to other administrative or adjudicative bodies before which the FCC is authorized to appear, when: (a) The FCC or any component thereof; or (b) any employee of the FCC in his or her official capacity; or (c) any employee of the FCC in his or her individual capacity where the DOJ or the FCC have agreed to represent the employee; or (d) the United States is a party to litigation or has an interest in such litigation, and the use of such records by the DOJ or the FCC is deemed by the FCC to be relevant and necessary to the litigation.

4. Law Enforcement and Investigation—To disclose pertinent information to the appropriate Federal, State, local, or tribal agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where the FCC becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

5. Congressional Inquiries—To provide information to a Congressional office from the record of an individual in response to an inquiry from that Congressional office made at the written request of that individual.

6. Government-wide Program Management and Oversight—To provide information to the General Services Administration (GSA) and/or the Government Accountability Office (GAO) for oversight purposes; to the National Archives and Records Administration (NARA) for use in its records management inspections; to the Department of Justice (DOJ) to obtain that department's advice regarding disclosure obligations under the Freedom of Information Act (FOIA); or to the Office of Management and Budget (OMB) to obtain that office's advice regarding obligations under the Privacy Act.

7. Breach Notification—To appropriate agencies, entities, and persons when: (a) The Commission suspects or has confirmed that there has been a breach of data maintained in the system of records; (b) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

8. Assistance to Federal Agencies and Entities—To another Federal agency or Federal entity, when the Commission determines that information from this system is reasonably necessary to assist the recipient agency or entity in: (a) Responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, program, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

9. Contract Services, Grants, or Cooperative Agreements—To disclose information to FCC contractors, grantees, or volunteers who have been engaged to assist the FCC in the performance of a contract service, grant, cooperative agreement, or other activity related to this system of records and who need to have access to the records in order to perform their activity.

REPORTING TO CONSUMER REPORTING AGENCIES:

In addition to the routine uses listed above, the Commission may share information from this system of records with a consumer reporting agency regarding an individual who has not paid a valid and overdue debt owed to the Commission, following the procedures set out in the Debt Collection Act, 31 U.S.C. 3701(e).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The information in this system includes:

1. Paper documents, records, and files (except OGE Form 450 files) that are maintained in file folders in file cabinets in the office suites of the Designated Federal Officers (DFOs) in the Bureaus and Offices (B/Os); these records are generally received electronically, and the DFOs are directed to scan, verify, and electronically file hard copies when received.

2. Electronic data, records, and files that are stored in the FCC's computer network databases; and

3. Original and any copies (paper format) of OGE Form 450 files, documents, and records are maintained in file folders in file cabinets in the OGC office suite.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

1. The FACA records (except OGE Form 450 files and associated vetting documents) are grouped primarily by the name of the FACA committee or subcommittee. Under this filing hierarchy, records are then retrieved by an individual's name; and

2. OGE Form 450 files and associated vetting documents are retrieved by the individual's name or other programmatic identifier assigned to the individual on whom they are maintained.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The information in this system is maintained and disposed of in accordance with the National Archives and Records Administration (NARA) General Records Schedule DAA–GRS–2015–0001 (GRS 6.2) Federal Advisory Committee Records:

- Substantive Committee Records
  - Records documenting the establishment and formation of committees and their significant actions and decisions. Refer to agency administrative procedures to ascertain if these records are held by the CMO, or DFO. Only one copy of each record is considered permanent. These are Permanent records and will be transferred to the National Archives at the time that related permanent records are transferred (DAA–GRS–2015–0001–0001).
- Substantive Audiovisual Records
  - Records include audiotapes, videotapes, and/or other recordings of meetings and hearings not fully transcribed; captioned formal and informal analog or digital photographs, and any related finding aids, of committee members and staff, meetings, or hearings; and posters (2 copies) produced by or for the committee. These

are Permanent records and will be transferred to the National Archives at the time that related permanent records are transferred (DAA–GRS–2015–0001–0002).

• Committee Accountability Records

○ Records that document financial and ethics accountability, such as records documenting financial expenditures associated with the functioning of the committee and financial disclosure and conflict of interest documents. These are Temporary records that do not contain unique information of historical value and are destroyed or deleted when six years old or when no longer required for business purposes (DAA–GRS–2015–0001–0004).

• Non-substantive Committee Records

○ Records related to specific committees that are of an administrative nature or are duplicative of information maintained elsewhere. These are Temporary records to be destroy when superseded, obsolete, no longer needed, or upon termination of the committee, whichever is sooner. (DAA–GRS–2015–0001–0005).

• Committee Management Records

○ Records created and/or maintained by Committee Management Officers (CMOs) and their staff related to the overall management of committees for an agency. These records may pertain to specific committees or to the committee management function in general. These are Temporary records to be destroy when 3 years old, 3 years after submission of report, or 3 years after superseded or obsolete, as appropriate. Longer retention is authorized if required for business use. (DAA–GRS–2015–0001–0006).

The FCC disposes of the paper documents by shredding. The electronic records, files, and data are destroyed either by physical destruction of the electronic storage media or by erasure of the data.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

1. FACA paper records documents, records, and files (except OGE Form 450 files) are maintained in file cabinets in the office suites of the DFO's Bureau or Office (B/O). These file cabinets are locked at the end of each business day. Access to each office suite is through a card-coded main door. Access to these files is restricted to the PERM supervisors and staff and to the DFO's authorized supervisors and staff in each Bureau or Office;

2. Paper copies of OGE Form 450 files, documents, and records are maintained in file cabinets in the OGC office suite. These file cabinets are locked at the end of each business day. Access to the OCG OGC office suite is through a card-coded main door. Access to these files is restricted to OGC supervisors and staff; and

3. Access to non-public FACA electronic records, files, and data, which are housed in the FCC's computer network databases, is restricted to authorized PERM supervisors and staff; to the supervisors and staff in each DFO's Bureau/Office; to the OGC supervisors and staff for OGE Form 450 files and associated vetting documentation; and to the Information Technology (IT) staff and contractors, who maintain the FCC's computer network. Other FCC employees and contractors may be granted access only on a ''need-to-know'' basis. The records in the FCC's computer network are protected by the FCC's security protocols, which include controlled access, passwords, and other IT safety and security features.

RECORDS ACCESS PROCEDURES:

Individuals wishing to request access to and/or amendment of records about themselves should follow the Notification Procedure below.

CONTESTING RECORD PROCEDURES:

Individuals wishing to request an amendment of records about themselves should follow the Notification Procedure below.

NOTIFICATION PROCEDURE:

Individuals wishing to determine whether this system of records contains information about themselves may do so by writing to Privacy Team, Federal Communications Commission, 45 L Street NE, Washington, DC 20554, or *Privacy@fcc.gov*.

Individuals requesting access must also comply with the FCC's Privacy Act regulations regarding verification of identity to gain access to the records (47 CFR part 0, subpart E).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The FCC last gave full notice of this system of records, FCC/OMD–3, Federal Advisory Committee Act (FACA) Membership Files, by publication in the **Federal Register** on October 13, 2013 (78 FR 63196).

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

[FR Doc. 2020–24730 Filed 11–6–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Notice of Board Meeting

DATES: November 16, 2020 at 10:00 a.m.

ADDRESSES: Telephonic. Dial-in (listen only) information: Number: 1–877–446–3914, Code: 2094665.

FOR FURTHER INFORMATION CONTACT: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

SUPPLEMENTARY INFORMATION: Board Meeting Agenda

Open Session

1. Approval of the October 19, 2020 Board Meeting Minutes
2. Monthly Reports
   (a) Investment Performance
   (b) Legislative Report
3. Quarterly Reports
   (c) Metrics
4. Multi-Asset Manager Update
   Adjourn

Dated: November 4, 2020.

Dharmesh Vashee,

Acting General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2020–24779 Filed 11–6–20; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. 201–0014]

Stryker and Wright Medical; Analysis of Consent Orders To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before December 9, 2020.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: ''Stryker and Wright Medical; File No. 201 0014'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your

comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Jonathan Ripa (202–326–2230), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis of Agreement Containing Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website at this web address: *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 9, 2020. Write ''Stryker and Wright Medical; File No. 201 0014'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Due to the public health emergency in response to the COVID–19 outbreak and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Stryker and Wright Medical; File No. 201 0014'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on *https://www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing this matter. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 9, 2020. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Consent Orders To Aid Public Comment

I. Introduction

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Stryker Corporation (''Stryker'') designed to remedy the anticompetitive effects resulting from Stryker's proposed acquisition of Wright Medical Group N.V. (''Wright''). The proposed Decision and Order (''Order'') contained in the Consent Agreement requires Stryker to divest all rights and assets related to its total ankle replacement and finger joint implant businesses to DJO Global, Inc. (''DJO'').

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Under the terms of the Purchase Agreement dated November 4, 2019, Stryker will acquire all of the outstanding shares of Wright for a total equity value of approximately $4 billion (''the Acquisition''). The Commission's Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by substantially lessening competition in the U.S. markets for total ankle replacements and finger joint implants. The proposed Consent Agreement would remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the proposed Acquisition.

II. The Parties

Stryker is a global medical device company based in Kalamazoo, Michigan. Stryker organizes its business operations into three segments: Orthopedics; medical and surgical; and neurotechnology and spine.

Headquartered in Amsterdam, the Netherlands, Wright is a global medical device company focused on extremities

and biologics products. Wright divides its business into four categories: Upper extremities; lower extremities; biologics products; and sports medicine.

III. The Relevant Products and Market Structures

a. Total Ankle Replacements

Total ankle replacements are used to treat end-stage ankle arthritis, in which the cartilage on the tibia (shin), talus (top of the foot), and fibula (calf) bones that form the ankle joint has worn away to create bone-on-bone grinding. Patients with end-stage ankle arthritis—typically aged fifty and older—experience severe pain and swelling of the ankle along with difficulty walking. Total ankle replacements reduce pain while maintaining, and even increasing, ankle motion. In a total ankle replacement procedure, a surgeon removes damaged portions of bone and cartilage and replaces it with a three-piece system. A metal tibial tray, a metal talar dome, and a plastic insert (polyethylene bearing) mimic the cartilage in the joint. In a fixed bearing total ankle replacement, the polyethylene bearing is locked to the tibial component, while in a mobile bearing system it moves independently. Physicians and their patients would not switch to an alternative product or therapy in response to a small but significant increase in the price of total ankle replacements.

Wright and Stryker are the first and third-largest suppliers in the United States, respectively, of total ankle replacements, while Integra LifeSciences (''Integra'') is the second-largest supplier. Exactech, Inc. and Zimmer Biomet also supply total ankle replacement products but have only small shares of the U.S. ankle replacement market. Together, Stryker and Wright would account for approximately 75 percent of the market.

b. Finger Joint Implants

Finger joint implants are used to treat advanced osteoarthritis and are implanted into a patient's proximal interphalangeal joints or metacarpophalangeal joints through a surgical procedure to replace damaged bone and cartilage. Arthritis is a gradual, progressive condition typically treated in stages. Physicians seek to use the least invasive treatment option possible to meet each patient's needs, using finger joint implants only when all other options have failed. Physicians and their patients would not switch to an alternative product or therapy in response to a small but significant increase in the price of finger joint implants.

Stryker and Wright are two of only three significant suppliers for finger joint implants in the United States. Integra is the leading supplier while Stryker and Wright are the second and third-largest suppliers, respectively. BioPro Implants (''BioPro'') is the only other supplier of finger joint implants in the United States but has a very small share of the U.S. finger joint implant market. The combined Stryker and Wright would have a market share in the United States in excess of 50 percent.

III. The Relevant Geographic Markets

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. Total ankle replacements and finger joint implants are medical devices regulated by the U.S. Food and Drug Administration (''FDA''). As such, total ankle replacements and finger joint implants sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

IV. Competitive Effects of the Acquisition

The proposed Acquisition would likely result in substantial competitive harm to consumers in the markets for total ankle replacements and finger joint implants. As suppliers of close substitutes in each relevant market, Stryker and Wright respond directly to competition from each other with improved products, better service, and lower prices. By eliminating this direct and substantial head-to-head competition, the proposed Acquisition likely would allow the combined firm to exercise market power unilaterally, resulting in less innovation and higher prices for consumers.

V. Entry Conditions

Entry in the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. To enter or effectively expand in either relevant market successfully, a supplier would need to design and manufacture an effective product, obtain FDA approval, and develop clinical history supporting the long-term efficacy of its product. The new entrant or expanding firm would also need to develop and foster product loyalty and establish a nationwide sales network capable of marketing the product and providing on-site service at hospitals nationwide. Establishing a track record for quality, service, and consistency is difficult, expensive, and typically requires several years.

VI. The Consent Agreement

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring the parties to divest to DJO all of the rights and assets needed for it to become an independent, viable, and effective competitor in the U.S. markets for total ankle replacements and finger joint implants. The divestitures will maintain the competition that currently exists in each of the relevant markets.

DJO is well positioned to restore the competition that otherwise would be lost through the proposed Acquisition. Headquartered in Vista, California, DJO is a global medical device company that has experience manufacturing, marketing, and distributing orthopedic devices in the United States, and a track record for quality, service, and consistency. DJO's lower and upper extremity product portfolio is also highly complementary to Stryker's total ankle replacements and finger joint implants.

The Order requires Stryker to divest all assets related to the divested businesses other than real property and tangible personal property. The divested assets include all inventory, contracts, permits, intellectual property (''IP''), and business information related to Stryker's total ankle replacement and finger joint implant products. Certain IP, which Stryker uses for both the divested products as well as retained products, will be retained by Stryker and licensed to DJO.

To ensure continuity for customers, the Order requires that Stryker supply DJO with transition assistance sufficient to efficiently transfer the total ankle replacement and finger joint implant assets to DJO and to assist DJO in operating the assets and business, in all material respects, in the manner in which Stryker did prior to the proposed Acquisition. Until DJO obtains FDA approval to become the legal manufacturer of the products, Stryker will act as an intermediary supplier for DJO. Further, the Order requires that the parties transfer all confidential business information to DJO, as well as provide access to employees who possess or are able to identify such information. DJO also will have the right to interview and offer employment to employees associated with the relevant products.

The parties must accomplish these divestitures and relinquish their rights to DJO no later than ten days after the proposed Acquisition is consummated.

If the Commission determines that DJO is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to DJO and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The Order also requires the parties to appoint Justin Menezes, from Mazars, as interim monitor to ensure the parties comply with the obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the assets and rights to DJO.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

[FR Doc. 2020–24813 Filed 11–6–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3404–PN]

Medicare and Medicaid Programs: Application From the Joint Commission for Continued Approval of Its Hospice Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from the Joint Commission for continued recognition as a national accrediting organization for hospices that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 9, 2020.

ADDRESSES: In commenting, refer to file code CMS–3404–PN.

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–3404–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

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–3404–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Caecilia Blondiaux, (410) 786–2190.

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. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice, provided that certain requirements are met by the hospice. Section 1861(dd) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospice. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 418 specify the conditions that a hospice must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for hospice services.

Generally, to enter into an agreement, a hospice must first be certified by a State survey agency (SA) as complying with the conditions or requirements set forth in part 418. Thereafter, the hospice is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

However, section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national Accrediting Organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at §§ 488.4 and 488.5. The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The Joint Commission's current term of approval for their hospice accreditation program expires June 18, 2021.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and regulations at § 488.5 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures;

resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the Joint Commission's request for continued approval of its hospice accreditation program. This notice also solicits public comment on whether the Joint Commission's requirements meet or exceed the Medicare conditions of participation (CoPs) for hospices.

III. Evaluation of Deeming Authority Request

The Joint Commission submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospices accreditation program. This application was determined to be complete on August 26, 2020. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of the Joint Commission will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of the Joint Commission's standards for hospices as compared with CMS' hospice CoPs.
- The Joint Commission's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of the Joint Commission's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ The Joint Commission's processes and procedures for monitoring hospices, which are found out of compliance with the Joint Commission's program requirements. These monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the SA monitors corrections as specified at § 488.9.

++ The Joint Commission's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ The Joint Commission's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of the Joint Commission's staff and other resources, and its financial viability.

++ The Joint Commission's capacity to adequately fund required surveys.

++ The Joint Commission's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced.

++ The Joint Commission's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ The Joint Commission's agreement to provide CMS with a copy of the most current accreditation survey, together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: October 29, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–24859 Filed 11–6–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10756, CMS–R–246]

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 January 8, 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–10576 Results of Your Drug Coverage Request

CMS–R–246 Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

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:* New Collection (Request for a new OMB control number); *Title of Information Collection:* Results of Your Drug Coverage Request; *Use:* The purpose of this notice is to provide information to enrollees whenever a Medicare Advantage Prescription Drug plan (MA–PD) covers a prescription drug under a different Medicare benefit than was requested by the enrollee. The enrollee may request coverage under their Part B or Part D benefit. When the MA–PD approves coverage in the benefit that was not requested by the beneficiary, the determination involves both an approval and a denial of benefits. The plan must send written notification that is readable, understandable, and explains the specific reasons for the denial of the alternate benefit. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process.

This collection replaces the current forms for communicating coverage provided to Medicare Advantage Prescription Drug (MA–PD) enrollees with regard to Part B vs. Part D drug requests. The new notice, Results of Your Drug Coverage Request, provides both approval messaging and the required denial messaging to beneficiaries in a more readable and understandable format than the existing Part D denial notice (CMS–10146, OMB–0938–0976) and Integrated Denial Notice (CMS–10003, OMB–0938–0829). Currently, coverage for drugs that are subject to a Part B vs. Part D adjudication is communicated by two separate forms: CMS–10146 (OMB–0938–0976) (communicating denial under Part D) and CMS–10003 (OMB–0938–0829) (communicating denial under Part B).

This proposed collection corrects this confusion by satisfying the denial and approval requirement in one form that brings focus to the approval rather than the denial. This proposed collection consolidates and streamlines the communication with enrollees by requiring one notice for communication when a drug request is subject to coordination of Part B and Part D benefits under 42 CFR 422.112. This collection is structured so that the enrollee receives a single notice that communicates both approval and denial under the respective benefits. *Form Number:* CMS–CMS–10756 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 755; *Total Annual Responses:* 68,413; *Total Annual Hours:* 17,103. (For policy questions regarding this collection contact Trevor Rose at 410–786–7768.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey; *Use:* The Centers for Medicare & Medicaid Services (CMS) has authority to collect various types of quality data under section 1852(e) of the Act and use this information to develop and publicly post a 5-star rating system for Medicare Advantage (MA) plans based on its authority to disseminate comparative information, including about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act. As codified at § 422.152(b)(3), Medicare health plans are required to report on quality performance data which CMS can use to help beneficiaries compare plans. Cost plans under section 1876 of the Act are also included in the MA Star Rating system, as codified at § 417.472(k), and are required by regulation (§ 417.472(j)) to make CAHPS survey data available to CMS.

The MMA under Sec. 1860D–4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys of enrollees in MA and Part D contracts and report the results to Medicare beneficiaries prior to the annual enrollment period. This request for approval is for CMS to continue conducting the Medicare CAHPS surveys annually to meet the requirement to conduct consumer satisfaction surveys regarding the experiences of beneficiaries with their health and prescription drug plans.

The primary purpose of the Medicare CAHPS surveys is to provide information to Medicare beneficiaries to help them make more informed choices among health and prescription drug plans available to them. Survey results are reported by CMS in the Medicare & You handbook published each fall and on the Medicare Plan Finder website. Beneficiaries can compare CAHPS scores for each health and drug plan as well as compare MA and FFS scores when making enrollment decisions. The Medicare CAHPS also provides data to help CMS and others monitor the quality and performance of Medicare health and prescription drug plans and identify areas to improve the quality of care and services provided to enrollees of these plans. CAHPS data are included in the Medicare Part C & D Star Ratings and used to calculate MA Quality Bonus Payments. *Form Number:* CMS–R–246 (OMB control number: 0938–0732);

Frequency: Yearly; Affected Public: Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 537; *Total Annual Responses:* 745,350; *Total Annual Hours:* 179,108. (For policy questions regarding this collection contact Sarah Gaillot at 410–786–4637.)

Dated: November 4, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–24852 Filed 11–6–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4195–PN]

Medicare Program; Request for Renewal of Deeming Authority of the National Committee for Quality Assurance (NCQA) for Medicare Advantage Health Maintenance Organizations and Preferred Provider Organizations

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Notice with request for comment.

SUMMARY: This proposed notice announces that CMS is considering granting approval of the National Committee for Quality Assurance's (NCQA) renewal application for Medicare Advantage ''deeming authority'' of Health Maintenance Organizations (HMOs) and Preferred Provider Organizations (PPOs). If approved, this new 6-year term of approval would be announced in a subsequent final notice. This proposed notice also announces a 30-day period for the public to submit comments on NCQA's application.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. December 9, 2020.

ADDRESSES: In commenting, refer to file code CMS–4195–PN.

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–4195–PN, 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–4195–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Greg McDonald, (410) 786–8941; or Nick Proy, (410) 786–8407.

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.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services through a Medicare Advantage (MA) organization that contracts with CMS. The regulations specifying the Medicare requirements that must be met for a Medicare Advantage organization (MAO) to enter into a contract with CMS are located at 42 CFR part 422. These regulations implement Part C of Title XVIII of the Social Security Act (the Act), which specifies the services that an MAO must provide and the requirements that the organization must meet to be an MA contractor. Other relevant sections of the Act are Parts A and B of Title XVIII and Part A of Title XI pertaining to the provision of services by Medicare-certified providers and suppliers. Generally, for an entity to be an MA organization, the organization must be licensed by the state as a risk bearing organization, as set forth in 42 CFR part 422.

As a method of assuring compliance with certain Medicare requirements, an MA organization may choose to become accredited by a CMS-approved accreditation organization (AO). By virtue of its accreditation by a CMS-approved AO, the MA organization may be ''deemed'' compliant in one or more requirements set forth in section 1852(e)(4)(B) of the Act. For CMS to recognize an AO's accreditation program as establishing an MA plan's compliance with our requirements, the AO must prove to CMS that their standards are at least as stringent as Medicare requirements for MA organizations. MA organizations that are licensed as health maintenance organizations (HMOs) or preferred provider organizations (PPOs) and are accredited by an approved accreditation organization may receive, at their request, ''deemed'' status for CMS requirements for the deemable areas. At this time, recognition of accreditation does not include the Part D areas of review set out at 42 CFR 423.165(b). AOs that apply for MA deeming authority are generally recognized by the health care industry as entities that accredit HMOs and PPOs. As we specify at § 422.157(b)(2)(ii), the term for which an AO may be approved by CMS may not exceed 6 years. For continuing approval, the AO must apply to CMS to renew their ''deeming authority'' for a subsequent approval period.

The National Committee for Quality Assurance (NCQA) was previously approved by CMS as an accreditation organization for MA deeming of HMOs and PPOs for a term to begin on October 19, 2014. That term lapsed on October 18, 2020, prior to our decision on its renewal application. On May 22, 2020, NCQA submitted its initial application to renew its deeming authority. On that same date, NCQA submitted materials requested by CMS that included information intended to address the requirements set out in our regulations at § 422.158(a) and (b) that are prerequisites for receiving approval of its accreditation program from CMS. CMS subsequently requested that additional materials be submitted by NCQA to satisfy these requirements.

II. Provisions of the Proposed Notice

The purpose of this proposed notice is to notify the public of NCQA's request to renew its Medicare Advantage deeming authority for HMOs and PPOs. NCQA submitted all the necessary materials (including its standards and monitoring protocol) to enable us to make a determination concerning its request for approval as an accreditation organization for CMS. This renewal application was determined to be complete on August 28, 2020. Under section 1852(e)(4) of the Act and § 422.158 (federal review of accreditation organizations), our review and evaluation of NCQA will be conducted as discussed below.

A. Components of the Review Process

The review of NCQA's renewal application for approval of MA deeming authority includes, but is not limited to, the following components:

• The types of MA plans that it would review as part of its accreditation process.

• A detailed comparison of NCQA's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk) in the following 5 areas: Quality Improvement, Anti-Discrimination, Confidentiality and Accuracy of Enrollee Records, Information on Advance Directives, and Provider Participation Rules.

• Detailed information about the organization's survey process, including—

++ Frequency of surveys and whether surveys are announced or unannounced.

++ Copies of survey forms, and guidelines and instructions to surveyors.

++ Descriptions of—

— The survey review process and the accreditation status decision making process;

— The procedures used to notify accredited MA organizations of deficiencies and to monitor the correction of those deficiencies; and

— The procedures used to enforce compliance with accreditation requirements.

• Detailed information about the individuals who perform surveys for the accreditation organization, including—

++ The size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

++ The education and experience requirements surveyors must meet;

++ The content and frequency of the in-service training provided to survey personnel;

++ The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

++ The organization's policies and practice for the participation, in surveys or in the accreditation decision process, by an individual who is professionally or financially affiliated with the entity being surveyed.

• A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

• A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

• A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

• A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.

• A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.

• A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization.

• The name and address of each person with an ownership or control interest in the accreditation organization.

• CMS will also consider NCQA's past performance in the deeming program and results of recent deeming validation reviews or equivalency reviews conducted as part of continuing federal oversight of the deeming program under § 422.157(d).

B. Notice Upon Completion of Evaluation

Upon completion of our evaluation, including a review of comments received as a result of this proposed notice, we will publish a notice in the **Federal Register** announcing the result of our evaluation. Section 1852(e)(4)(C) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of a completed application to complete our survey activities and application review process. At the end of the 210-day period, we will publish an approval or denial of the application in the **Federal Register**.

III. Collection of Information Requirements

This document does not impose any new or revised ''collection of information'' requirements or burden. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). With respect to the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–24799 Filed 11–5–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; State Plan for Grants to States for Refugee Resettlement (OMB #0970–0351)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR) is requesting a 3-year extension of the ACF form ORR–0135 State Plan for Grants to States for Refugee Resettlement (OMB #0970–0351, expiration 3/31/2021). ORR is proposing changes to the form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be

obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: A State Plan is a required comprehensive narrative description of the nature and scope of a state's or Replacement Designee's (RD) Refugee Resettlement Program and provides assurances that the program will be administered in conformity with the specific requirements stipulated in 45 CFR 400.4–400.9. The State Plan must include all applicable state or RD procedures, designations, and certifications for each requirement as well as supporting documentation. The plan assures ORR that the state or RD is capable of administering refugee assistance and coordinating employment and other social services for eligible caseloads in conformity with specific requirements.

Changes proposed to the previously approved State Plan for Grants to States for Refugee Resettlement information collection are described below. ORR is proposing:

- Streamlining/formatting changes to multiple sections of the form including technical corrections to regulatory citations and removing a number of requirements related to the now obsolete Wilson-Fish Alternative Program (superseded by the Wilson-Fish TANF Coordination Program, which will have its own separate reporting requirements).
- adding a number of requirements related to Replacement Designees (RDs) to ensure that they are administering the Refugee Resettlement Program with transparency and equity and to the same standard as a state, including quarterly consultation process, Refugee Medical Assistance, Unaccompanied Refugee Minors (URM), and emergency planning to ensure ORR populations receive all necessary information and services to the extent possible.
- requesting additional information related to the Refugee Support Services (RSS) program; ORR's current template does not provide sufficient detailed information for ORR to ascertain how a grantee intends to provide RSS services to its client base.
- improving the URM section to correct inefficiencies, eliminate unnecessary items, and address the needs of victims of trafficking and Special Immigrant Juveniles now eligible for the URM program. In particular, ORR is soliciting states' and RDs' plans for placing children referred by ORR and ensuring alignment with federal capacity priorities.

Respondents: State agencies and RDs under 45 CFR 400.301(c) administering or supervising the administration of programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
State Plan for Grants to States for Refugee Resettlement	62	3	18	3,348	1,116

Estimated Total Annual Burden Hours: 1,116.

Comments: The Department specifically requests 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 shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) [Title IV, Sec. 412 of the Act] for each state agency requesting federal funding for refugee resettlement under 8 U.S.C. 524 [Title IV, Sec. 414 of the Act].

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–24777 Filed 11–6–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2268]

Insanitary Conditions at Compounding Facilities; Guidance for Industry; 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 entitled ''Insanitary Conditions at Compounding Facilities.'' Drug products compounded under insanitary conditions could become contaminated and cause serious adverse events, including death, in patients. FDA is issuing this guidance to help compounding facilities and State regulatory agencies understand some examples of what FDA considers to be insanitary conditions that could cause a drug to become contaminated or rendered injurious to health. These examples are intended to help compounding facilities take action to prevent the occurrence of these and other insanitary conditions, as well as to implement appropriate corrective actions when such conditions already exist.

DATES: The announcement of the guidance is published in the **Federal Register** on November 9, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances on any guidance 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–2016–D–2268 for ''Insanitary Conditions at Compounding Facilities.'' 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.

• 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.

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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

FOR FURTHER INFORMATION CONTACT: Jinhee Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5225, Silver Spring, MD 20993, 301–796–6770.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Insanitary Conditions at Compounding Facilities.'' [1] Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(A)), a drug is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Drug products compounded under insanitary conditions could become contaminated and cause serious adverse events, including death, in patients. Although sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b) provide exemptions for compounded drugs from specified provisions of the FD&C Act if certain conditions are met, neither section provides an exemption from section 501(a)(2)(A) of the FD&C Act. Any drug that is prepared, packed, or held under insanitary conditions is deemed to be adulterated under the FD&C Act, including drugs produced by a compounding facility.

Since the 2012 fungal meningitis outbreak associated with injectable drug products that a pharmacy compounded and shipped to patients and healthcare providers across the country, the Agency has identified insanitary conditions at many of the compounding facilities that it has inspected, and numerous compounders have voluntarily recalled drug products intended to be sterile and also temporarily or permanently ceased sterile operations because of these findings. Generally, State licensed pharmacies do not register with FDA unless they are outsourcing facilities. As a result, the Agency is often not aware of these pharmacies, their conditions and practices, and potential problems with the quality of their drug products. Although FDA does conduct some surveillance inspections, FDA does not inspect the vast majority of State licensed pharmacies in the United States unless, for example, FDA receives a complaint, such as a report of a serious adverse event or product quality issue. FDA does, however, routinely inspect outsourcing facilities registered with FDA.[2] Regardless of whether a facility is routinely inspected by FDA, it is critical that both State licensed pharmacies and outsourcing facilities identify and remediate, as well as work to prevent, the occurrence of insanitary conditions within their facilities. Because insanitary conditions can result in drug contamination and patient injury, corrective action should be implemented expeditiously in order to prevent the recurrence of such conditions.

In the **Federal Register** of September 26, 2018 (83 FR 48631), FDA announced the availability of a revised draft guidance for industry entitled ''Insanitary Conditions at Compounding Facilities.'' The revised draft guidance provided examples of conditions that the Agency has observed at compounding facilities it has inspected and considers to be insanitary conditions. The revised draft guidance also described corrective actions that compounding facilities should take when they identify such conditions and the regulatory actions FDA may take in response to identified insanitary conditions.

FDA received comments on the revised draft guidance from various

[1] For the purpose of this guidance, FDA regards *compounding facilities* as pharmacies, Federal facilities, and outsourcing facilities that compound or repackage drugs, or that mix, dilute, or repackage biological products.

[2] See section 503B(b)(4) of the FD&C Act.

stakeholders (*e.g.,* physicians, pharmacies, outsourcing facilities). Several comments were submitted concerning the implications of the policies described in the revised draft guidance for physicians who compound or repackage drug products or mix, dilute, or repackage FDA-licensed biological products in their offices. In response to these comments, FDA made changes, where appropriate, in the final guidance. The changes include adding a footnote to state that ''processing of beta-lactams'' does not refer to mixing, reconstituting, or other such acts that are performed in accordance with the directions contained in FDA-approved labeling; adding a footnote to reflect that the FDA does not generally object to rapid movement temporary blocking or disruption of first air in the ISO 5 area when necessary for the safe handling of radiopharmaceuticals to minimize radiation exposure, and revising the language in a footnote concerning the scope of physician compounding or repackaging activities to state that FDA generally does not intend to take action under section 501(a)(2)(A) of the FD&C Act against a physician who is compounding a drug product, repackaging an FDA-approved drug product, or who is mixing, diluting, or repackaging an FDA-licensed biological product, provided that it occurs in the physician's office for in-office administration to the physician's patients; and adding recommendations encouraging compounders to use risk evaluation strategies and risk management tools to develop appropriate controls necessary to prevent the occurrence of insanitary conditions at their facilities. In addition, editorial changes were made to the guidance for clarity.

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 ''Insanitary Conditions at Compounding Facilities.'' The examples described in the final guidance do not constitute an exhaustive list of conditions FDA considers to be insanitary conditions. 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

This guidance contains no collection 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.

However, this guidance refers to a previously approved FDA collection of information. This collection of information is subject to review by OMB under the PRA. The collections of information in 21 CFR part 7 pertaining to FDA's recall regulations have been approved under OMB control number 0910–0249.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 3, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–24807 Filed 11–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Comments on Draft Recommendation Statement on Preventing Obesity in Midlife Women, as Part of the HRSA-Supported Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice seeks public comments on a draft recommendation statement on preventing obesity in midlife women, as part of the HRSA-supported Women's Preventive Services Guidelines (''Guidelines''), through a national cooperative agreement, the Women's Preventive Services Initiative (WPSI). The WPSI recommends counseling midlife women, aged 40 to 60 years, with normal or overweight BMI (18.5–29.9 kg/m2) to maintain weight or limit weight gain to prevent obesity. Counseling may include individualized discussion of healthy eating and physical activity. Under Section 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act, non-grandfathered group health plans and non-grandfathered group and individual health insurance issuers must include coverage, without cost sharing, for certain preventive services under that section, including those provided for in the Guidelines.

DATES: Members of the public are invited to provide written comments no later than December 9, 2020. All comments received on or before this date will be reviewed and considered by the WPSI Multidisciplinary Steering Committee, and provided to HRSA for further consideration in determining the recommended updates that it will support.

ADDRESSES: Members of the public interested in providing comments can do so by accessing the initiative's web page at *https://www.womenspreventivehealth.org/.*

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone (301) 443–8283 or email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The HRSA-supported Women's Preventive Services Guidelines were originally established in 2011 based on recommendations from an HHS commissioned study by the Institute of Medicine, now known as the National Academy of Medicine (NAM). Since then, there have been advancements in science and gaps identified in the existing guidelines, including a greater emphasis on practice-based clinical considerations. HRSA awarded a 5-year cooperative agreement in March 2016 (HRSA–16–057) to convene a coalition representing clinicians, academics, and consumer-focused health professional organizations to conduct a rigorous review of current scientific evidence and recommend updates to existing guidelines, in accordance with the framework created by the NAM Clinical Practice Guidelines We Can Trust expert committee. The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative.

Under section 2713 of the Public Health Service Act, non-grandfathered group health plans and issuers of non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose. Non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual coverage are required to provide coverage without cost sharing for

preventive services listed in the updated HRSA-supported Guidelines.

Under HRSA's cooperative agreement with the American College of Obstetricians and Gynecologists, the WPSI administers processes which assure public input and transparency, as well as participation by patient and consumer representatives, in the development of these Guidelines.

Thomas J. Engels,

Administrator.

[FR Doc. 2020–24819 Filed 11–6–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The Advisory Council will next meet on Monday, November 9, and Tuesday, November 10. On November 9, federal representatives will provide updates on efforts to address Alzheimer's disease since January and a panel will present the results of two VA programs, STAR–VA and REACH–VA. On November 10, an invited panel will discuss past and current initiatives to expand access to long-term services and supports.

DATES: The meeting will be held on November 9 from 1:00 p.m. to 4:00 p.m. EST and November 10 from 1:00 p.m. to 4:00 p.m. EST.

ADDRESSES: The meeting will be virtual and stream live at *http://www.hhs.gov/live.*

Comments: Time is allocated on the agenda to hear public comments from 3:30 p.m. to 4:00 p.m. The time for oral comments will be limited to two (2) minutes per individual. In order to provide a public comment, please register by emailing your name to *napa@hhs.gov* by Thursday, November 5. Registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. Note: There may be a 30–45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 3:15 p.m. to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. All participant audio lines will be muted for the duration of the meeting and only unmuted by the Host at the time of the participant's public comment. Should you have questions during the session email *napa@hhs.gov* and someone will respond to your message as quickly as possible.

In order to ensure accuracy, please submit a written copy of oral comments for the record by emailing *napa@hhs.gov* by Thursday, November 12. These comments will be shared on the website and reflected in the meeting minutes.

In lieu of oral comments, formal written comments may be submitted for the record by Tuesday, November 10 to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, 202–260–6075, *helen.lamont@hhs.gov.* Note: The meeting will be available to the public live at *www.hhs.gov/live.*

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: An invited panel will present on emergency preparedness for people with dementia with a special focus on the COVID–19 pandemic. The chairs of the subcommittees (Research, Clinical Care, and Long-Term Services and Supports) will present recommendations for adoption by the full Advisory Council.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website when available, after the meeting.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel 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: October 13, 2020.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

[FR Doc. 2020–24818 Filed 11–6–20; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2020–0033; OMB No. 1660–0026]

Agency Information Collection Activities: Proposed Collection; Comment Request; State Administrative Plan for the Hazard Mitigation Grant Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: 60 day notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the State Administrative Plan for the procedural guide that details how the State will administer the Hazard Mitigation Grant Program (HMGP).

DATES: Comments must be submitted on or before January 8, 2021.

ADDRESSES: Submit comments at *www.regulations.gov* under Docket ID FEMA–2020–0033. Follow the instructions for submitting comments.

All submissions received must include the agency name and Docket ID, and will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Roselyn Brown-Frei, Section Chief, Hazard Mitigation Division, Federal Insurance and Mitigation Administration, FEMA, *roselyn.brown-frei@fema.dhs.gov,* 202–924–7198. You may contact the Information Management Division for copies of the proposed collection of information at

email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: FEMA regulations in 44 CFR 206.437 require development and updates to the State Administrative Plan by State Applicants/Recipients, as a condition of receiving HMGP funding under section 404 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170c. Applicant/Recipients can be any State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands, or an Indian Tribal government (federally-recognized) that chooses to act as an Applicant/Recipient. A State is defined in section 102(4) of the Stafford Act (42 U.S.C. 5122) as any State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Collection of Information

Title: State Administrative Plan for the Hazard Mitigation Grant Program.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660–0026.

FEMA Forms: None.

Abstract: The State Administrative Plan is a procedural guide that details how the State will administer the HMGP. The State, Territory, or Indian Tribal government (who acts as a recipient) must have a current administrative plan approved by the appropriate FEMA Regional Administrator before receiving HMGP funds. The administrative plan may take any form including a chapter within a comprehensive State mitigation program strategy.

Affected Public: State, Territories, and Tribal governments.

Estimated Number of Respondents: 35.

Frequency of Response: Twice Annually.

Estimated Number of Responses: 70.

Estimated Total Annual Burden Hours: 560.

Estimated Total Annual Respondent Cost: $32,704.

Estimated Respondents' Operation and Maintenance Costs: There are no Operation and Maintenance Costs associated with this information collection.

Estimated Respondents' Capital and Start-Up Costs: There are no record keeping, capital, start-up or maintenance costs associated with this information collection.

Estimated Total Annual Cost to the Federal Government: $23,871.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Maile Arthur,

Acting Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2020–24845 Filed 11–6–20; 8:45 am]

BILLING CODE 9111–BW–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2007–0008]

National Advisory Council; Meeting

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Committee Management; notice of open Federal Advisory Committee meeting.

SUMMARY: The Federal Emergency Management Agency's National Advisory Council (NAC) will meet December 1–2, 2020. The meeting will be open to the public through virtual means.

DATES: The NAC will meet by virtual means Tuesday, December 1 and Wednesday, December 2, 2020, between 12:30 p.m. to 5 p.m. Eastern Time (ET). Please note that the meeting may close early if the NAC has completed its business.

ADDRESSES: All membership, FEMA, invited guest and public participation is by virtual means only. Anyone who wishes to participate must register with FEMA prior to the meeting by providing their name, telephone number, email address, title, and organization to the person listed in the **FOR FURTHER INFORMATION CONTACT** caption by 5 p.m. ET Friday, November 27, 2020.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered by the NAC. The topic areas are indicated in the **SUPPLEMENTARY INFORMATION** caption. The full agenda and any related documents for this meeting will be available by Friday, November 27, 2020, by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** caption. Written comments must be submitted and received by 5 p.m. ET on November 27, 2020, identified by Docket ID FEMA–2007–0008, and submitted by the following method: Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions must include the words ''Federal Emergency Management Agency'' and the docket ID for this action. Comments received, including any personal information provided, will be posted without alteration at *http://www.regulations.gov.* You may wish to read the ''Privacy & Security Notice'' found via a link on the homepage of *www.regulations.gov.*

Docket: For access to the docket to read comments received by the NAC, go to *http://www.regulations.gov,* and search for Docket ID FEMA–2007–0008.

Public comment periods will be held on Tuesday, December 1, 2020, from 1:30 p.m. to 1:40 p.m. ET and on Wednesday, December 2, 2020, from 1:30 p.m. to 1:40 p.m. ET. All speakers must limit their comments to 3 minutes. Comments should be addressed to the NAC. Any comments not related to the agenda topics will not be considered by the NAC. To register to make remarks during the public comment period, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** caption by 5 p.m. ET Friday, November 27, 2020. Please note that the public comment period may end before the time indicated, following the last call for comments.

Reasonable accommodations are available for people with disabilities. To request a reasonable accommodation, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** caption as soon as possible. Last minute requests will be accepted but may not be possible to fulfill.

FOR FURTHER INFORMATION CONTACT: Jasper Cooke, Designated Federal Officer, Office of the National Advisory Council, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472–3184, telephone (202) 646–2700, and email *FEMA-NAC@fema.dhs.gov.* The NAC website is *http://www.fema.gov/national-advisory-council.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix.

The NAC advises the FEMA Administrator on all aspects of emergency management. The NAC incorporates input from State, local, territorial, and Tribal governments and the private sector in making recommendations to the FEMA Administrator to be considered and potentially incorporated into FEMA plans and strategies. The NAC includes a cross-section of officials, emergency managers, and emergency response providers from State, local, territorial, and Tribal governments, the private sector, and nongovernmental organizations.

Agenda: On Tuesday, December 1, 2020, the NAC will hear from participants and discuss expediting disaster assistance.

On Wednesday, December 2, 2020, the NAC will hear from participants and discuss creating an equity standard.

The full agenda and any related documents for this meeting will be available by Friday, November 27, 2020, by contacting the person listed in **FOR FURTHER INFORMATION CONTACT.**

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–24847 Filed 11–6–20; 8:45 am]

BILLING CODE 9111–48–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2020–0043]

Request for Information: Evidence-Building Activities

AGENCY: Department of Homeland Security.

ACTION: Request for information.

SUMMARY: The Foundations for Evidence-Based Policymaking Act of 2018 requires federal agencies to develop evidence-building plans to identify and address questions relevant to Agency policies, programs, regulations, management, and operations. Through this request for Information (RFI), the Department of Homeland Security (DHS) seeks to expand ongoing efforts to identify priority questions that can guide evidence-building activities by soliciting input from the public.

DATES: Please send comments on or before December 31, 2020. Comments received after that date will be considered to the extent practicable.

ADDRESSES: You may submit comments via the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the instructions for submitting comments via Docket No. DHS–2020–0043. All comments received, including any personal information provided, may be posted without change to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice, please contact Michael Stough, Director, Program Analysis and Evaluation, (202) 447–0518, *michael.stough@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Evidence Act

The Foundations for Evidence-Based Policymaking Act of 2018 (Evidence Act, Pub. L. 115–435) requires each federal agency to develop, as part of the agency strategic plan issued every four years,[1] a systematic evidence-building plan (or ''learning agenda'') to identify and address policy questions relevant to the programs, policies, and regulations of the agency.[2] The plan must contain (1) a list of policy-relevant questions for which the agency intends to develop evidence to support policymaking; (2) a list of data the agency intends to collect, use, or acquire to facilitate the use of evidence in policymaking; (3) a list of methods and analytical approaches that may be used to develop evidence to support policymaking; (4) a list of any challenges to developing evidence to support policymaking, including any statutory or other restrictions to accessing relevant data; (5) a description of the steps the agency will take to accomplish items (1) and (2) above; and (6) any other information as required by guidance issued by the Director of the Office of Management and Budget (OMB).[3] In developing the evidence-building plan, the agency must consult with stakeholders, including the public, agencies, State and local governments, and representatives of non-governmental researchers.[4]

DHS has commenced development of its evidence-building plan. Consistent with the Evidence Act, DHS now invites comments from the public to inform the development of the Department's evidence-building plan. DHS invites suggestions in many forms, such as questions to be answered, hypotheses to be tested, or problems to be studied. DHS will analyze information collected from this RFI to continue developing its evidence-building plan.

DHS Background

With the passage of the Homeland Security Act by Congress in November 2002, the Department of Homeland Security (DHS) became a Cabinet-level agency to unite the Nation's approach to homeland security. DHS combined functions of 22 different agencies with broad responsibilities that collectively prevent attacks, mitigate threats, respond to national emergencies, preserve economic security, and preserve legacy agency functions. DHS is committed to evaluating the effectiveness and efficiency of its programs, policies, and regulations. DHS will use its evidence-building plan to coordinate and communicate how evaluation, statistics, research, and analysis will be used to help the Department achieve its mission.

Request for Information

Through this RFI, DHS is soliciting suggestions from a broad array of stakeholders across public and private sectors that may be familiar with or interested in the work of DHS and wish to volunteer suggestions for studies that could help DHS improve the effectiveness and efficiency of DHS programs, policies and regulations. DHS invites suggestions in many forms—such as questions to be answered, hypotheses to be tested, or problems to be studied—and focused on any area of Department's work, including policy,

[1] The latest such DHS strategic plan covers the years 2020–2024, and preceded implementation of the Evidence Act. *See* DHS, The DHS Strategic Plan: Fiscal Years 2020–2024, *available at https://www.dhs.gov/sites/default/files/publications/19_0702_plcy_dhs-strategic-plan-fy20-24.pdf* (last visited Oct. 26, 2020).

[2] *See* 5 U.S.C. 306, 312.

[3] *See* 5 U.S.C. 312(a).

[4] *See, e.g..,* OMB Memorandum M–19–23, Phase 1 Implementation of the Foundations for Evidence Based Policymaking Act of 2018: Learning Agenda, Personnel, and Planning Guidance at 16–17 (July 10, 2019), *available at https://www.whitehouse.gov/wp-content/uploads/2019/07/M-19-23.pdf* (last visited Oct. 26, 2020) (''Agencies should gather input in the manner that best meets their needs, most effectively engages their specific stakeholders, and leverages existing activities and/or requirements whenever possible, in accordance with applicable law and policy. Potential models for doing so include: Requests for Information published in the **Federal Register**, listening sessions with groups of stakeholders, Technical Working Groups, and one-on-one consultations. OMB recognizes that agencies may use different approaches at different points in the process, and that it may not be feasible to engage all stakeholders for all updates to the learning agenda. . . .'').

programs, regulations, management, and operations. Responses to this RFI will inform the Department's ongoing development of a set of questions that will guide evidence-building activities, such as foundational research, policy analysis, performance measurement, and program evaluation.

This RFI is for information and planning purposes only and should not be construed as a solicitation or as creating or resulting in any obligation on the part of DHS.

Michael Stough,

Evaluation Officer, U.S. Department of Homeland Security.

[FR Doc. 2020–24836 Filed 11–6–20; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–NWRS–2020–N145; FF09R81000; OMB Control Number 1018–New]

Agency Information Collection Activities; U.S. Fish and Wildlife Service Agreements With Friends Organizations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing a new information collection in use without an OMB control number.

DATES: Interested persons are invited to submit comments on or before January 8, 2021.

ADDRESSES: Send your comments on the information collection request (ICR) by mail to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference OMB Control Number ''1018–Friends'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320, all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Service enters into agreements and partnerships with nonprofit Friends groups to facilitate and formalize collaboration between the parties in support of mutual goals and objectives as authorized by:

- The Fish and Wildlife Act of 1956 (16 U.S.C. 742a–742j);
- The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–ee), as amended;
- The Refuge Recreation Act of 1962 (16 U.S.C. 460k *et seq.*), as amended;
- The Anadromous Fish Conservation Act (16 U.S.C. 757a–757g), as amended;
- The Fish and Wildlife Coordination Act of 1934 (16 U.S.C. 661–667e), as amended;
- The National Wildlife Refuge System Volunteer and Community Partnership Enhancement Act of 1998 (16 U.S.C. 742f), as amended; and
- The National Fish Hatchery System Volunteer Act of 2006 (16 U.S.C. 760aa), as amended.

The Service utilizes a standardized agreement which describes the substantial involvement of both parties in mutually agreed-upon activities and ensures that both parties have a mutual understanding of their respective roles, responsibilities, rights, expectations, and requirements within the partnership. The agreement, pre-approved by the Department of the Interior (DOI) Office of the Solicitor, provides the suggested language common to most Service Friends partnerships. The content is based on DOI and Service policies, but the Friends and Service sites/programs may thoughtfully add and delete certain language to meet their varying partnership roles and responsibilities wherever Department and Service policies do not dictate otherwise. We also use a supplemental partnership agreement for use of Service property, which provides additional terms and responsibilities beyond the general terms of the partnership agreement and is required only for those Friends groups that use Service land, facilities, or equipment.

The partnership agreement and supplemental agreement are effective for 5 years, with four annual modification options during the 5-year period of performance. Each time the agreement is up for its 5-year renewal, the Refuge or Fish Hatchery Project Leader and the Friends President or Board will meet to review, modify, and sign the agreement as described above. To become effective, the Regional Director (or designee) must review, approve, and sign a new agreement every 5 years.

In addition to the partnership agreement and supplemental agreement, and subsequent renewals of the agreements, the Service collects the following information in conjunction with the administration of the Friends Program:

• Basic program information documentation, to include documents such as Internal Revenue Service (IRS) determination letters recognizing an organization as tax exempt, submission of IRS Form 990-series forms, bylaws, articles of incorporation, etc.;

• Internal financial control documentation for the organization;

• Recordkeeping requirements documenting accountability for donations and expenditures;

• Assurance documentation that donations, revenues, and expenditures benefit the applicable refuge or hatchery;

• Resumes of potential Friends group staff selected to work in visitor centers;

• Annual performance reporting (donations, revenues, and expenditures) and number of memberships (if applicable); and

• Additional information that may be included as part of quarterly, annual, and in-depth program reviews.

Over the life of this clearance, the Service plans to develop a digital platform and process to collect information directly from Friends groups. Until that occurs, Friends groups will submit information through form and non-form responses.

The Service uses the information collected to establish efficient and effective partnerships and working relationships with nonprofit Friends organizations. The agreements provide a method for the Service to legally accept donations of funds and other contributions by people and organizations through partnerships with nonprofit (and non-Federal) Friends organizations.

Title of Collection: U.S. Fish and Wildlife Service Agreements with Friends Organizations.

OMB Control Number: 1018–New.

Form Number: None.

Type of Review: Existing collection in use without an OMB control number.

Respondents/Affected Public: Private sector (nonprofit organizations).

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for agreements and associated documentation requirements. Annually for performance reports.

Total Estimated Annual Nonhour Burden Cost: None.

Requirement	Average number of annual respondents	Average number of responses each	Average number of annual responses	Average completion time per response (hours)	Estimated annual burden hours
Partnership Agreement:					
Private Sector	50	1	50	40	2,000
Renewal of Partnership Agreement:					
Private Sector	150	1	150	8	1,200
Supplemental Agreement:					
Private Sector	50	1	50	4	200
Renewal of Supplemental Agreement:					
Private Sector	150	1	150	2	300
Basic Program Documentation:					
Private Sector	200	1	200	8	1,600
Internal Financial Control Documentation:					
Private Sector	200	1	200	40	8,000
Donation and Expenditure Recordkeeping Requirements:					
Private Sector	200	1	200	20	4,000
Assurance Documentation:					
Private Sector	200	1	200	40	8,000
Friends Group Staff Resumes:					
Private Sector	25	1	25	8	200
Annual Performance Reports:					
Private Sector	200	1	200	20	4,000
Supplemental Documentation Requirements: Quarterly Review:					
Private Sector	200	4	800	2	1,600
Supplemental Documentation Requirements: Annual Review:					
Private Sector	10	1	10	20	200
Totals	*1,635*		*2,235*		*31,300*

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: November 4, 2020.

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2020–24802 Filed 11–6–20; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1229]

Certain Furniture Products Finished With Decorative Wood Grain Paper and Components Thereof; 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 2, 2020 under section 337 of the Tariff Act of 1930, as amended, on behalf of Toppan Interamerica, Inc. of McDonough, Georgia. Supplements to the complaint were filed on October 5, 2020, and October 21, 2020. The complaint, as supplemented, 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 furniture products finished with decorative wood grain paper and

components thereof by reason of infringement of U.S. Copyright Registration No. VA 2–142–287 (''the '287 copyright''). 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 a cease and desist order.

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 3, 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 the '287 copyright; 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 ''furniture products, including desks, bookcases, media stands and consoles, chairs, coat racks, buffets, beds, headboards, footboards, cabinets, coffee tables, dining tables, side tables and end tables, and components thereof, constructed from engineered wood products, such as particleboard and fiberboard, finished with a decorative wood grain paper'';

(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: Toppan Interamerica, Inc., 1131 Highway 155 South, McDonough, GA 30253.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Walker Edison Furniture Company, LLC, 4350 West 2100 South, Salt Lake City, UT 84120.

(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 3, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–24782 Filed 11–6–20; 8:45 am]

BILLING CODE 7020–02–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0121]

Information Collection: Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste and Reactor-Related Greater than Class C Waste.''

DATES: Submit comments by January 8, 2021. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject); however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0121. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear

Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0121 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0121.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement and burden spreadsheet are available in ADAMS under Accession Nos. ML20210M286 and ML20210M285.
- *Attention:* The PDR, where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0121 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Part 72 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High- Level Radioactive Waste, and Reactor-Related Greater than Class C Waste.''
2. *OMB approval number:* 3150–0132.
3. *Type of submission:* Revision.
4. *The form number, if applicable:* Not applicable.
5. *How often the collection is required or requested:* Required reports are collected and evaluated on a continuing basis as events occur; submittal of reports varies from less than one per year under some rule sections to up to an average of about 80 per year under other rule sections. Applications for new licenses, certificates of compliance (CoCs), and amendments may be submitted at any time; applications for renewal of licenses are required every 40 years for an Independent Spent Fuel Storage Installation (ISFSI) or CoC effective May 21, 2011, and every 40 years for a Monitored Retrievable Storage (MRS) facility.
6. *Who will be required or asked to respond:* Certificate holders and applicants for a CoC for spent fuel storage casks; licensees and applicants for a license to possess power reactor spent fuel and other radioactive materials associated with spent fuel storage in an ISFSI; and the Department of Energy for licenses to receive, transfer, package and possess power reactor spent fuel, high-level waste, and other radioactive materials associated with spent fuel and high-level waste storage in an MRS.
7. *The estimated number of annual responses:* 868 (628 reporting responses + 154 third-party disclosure responses + 86 recordkeepers).
8. *The estimated number of annual respondents:* 86.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 80,221 hours (33,712 reporting + 43,657 recordkeeping + 2,852 third-party disclosure).
10. *Abstract:* 10 CFR part 72, establishes mandatory requirements, procedures, and criteria for the issuance of licenses to receive, transfer, and possess power reactor spent fuel and other radioactive materials associated with spent fuel storage in an ISFSI, as well as requirements for the issuance of licenses to the Department of Energy to receive, transfer, package, and possess power reactor spent fuel and high-level radioactive waste, and other associated radioactive materials in an MRS. The information in the applications, reports, and records is used by NRC to make licensing and other regulatory determinations.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: November 4, 2020.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2020–24797 Filed 11–6–20; 8:45 am]

BILLING CODE 7590–01–P

PEACE CORPS

Information Collection Request; Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. In accordance with the Paperwork Reduction Act of 1995 and implementing OMB guidance, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 30 days for public comment in the **Federal Register** preceding submission to OMB.

DATES: Submit comments on or before December 9, 2020.

ADDRESSES: Address written comments and recommendations for the proposed information collection to Virginia Burke, FOIA/Privacy Act Officer, by email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Virginia Burke, FOIA/Privacy Act Officer, at (202) 692–1887, or *PCFR@peacecorps.gov.*

SUPPLEMENTARY INFORMATION:

Title: Individual Specific Medical Evaluation Forms (15).

OMB Control Number: 0420–0550.

Type of Request: Revision/New.

Affected Public: Individuals/Physicians.

Respondents Obligation to Reply: Voluntary.

Respondents: Potential and current volunteers.

Burden to the Public:

- Asthma Evaluation Form
  - (a) Estimated number of Applicants/physicians—700/700
  - (b) Frequency of response—one time
  - (c) Estimated average burden per response—75 minutes/30 minutes
  - (d) Estimated total reporting burden—875 hours/350 hours
  - (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: When an Applicant reports on the Health History Form any history of asthma, he or she will be provided an Asthma Evaluation Form for the treating physician to complete. The Asthma Evaluation Form asks for the physician to document the Applicant's condition of asthma, including any asthma symptoms, triggers, treatments, or limitations or restrictions due to the condition. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of the Applicant within reasonable proximity to a hospital in case treatment is needed for a severe asthma attack.

- Diabetes Diagnosis Form
  - (a) Estimated number of Applicants/physicians—55/55
  - (b) Frequency of response—one time
  - (c) Estimated average burden per response—75 minutes/30 minutes
  - (d) Estimated total reporting burden—69 hours/28 hours
  - (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: When an Applicant reports the condition of diabetes Type 1 on the Health History Form, the Applicant will be provided a Diabetes Diagnosis Form for the treating physician to complete. In certain cases, the Applicant may also be asked to have the treating physician complete a Diabetes Diagnosis Form if the Applicant reports the condition of diabetes Type 2 on the Health History Form. The Diabetes Diagnosis Form asks the physician to document the diabetes diagnosis, etiology, possible complications, and treatment. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer assignment and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of an Applicant who requires the use of insulin in order to ensure that adequate insulin storage facilities are available at the Applicant's site.

- Transfer of Care—Request for Information Form
  - (a) Estimated number of Applicants/physicians—1,270/1,270
  - (b) Frequency of response—one time
  - (c) Estimated average burden per response—75 minutes/30 minutes
  - (d) Estimated total reporting burden—1,588 hours/635 hours
  - (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: When an Applicant reports on the Health History Form a medical condition of significant severity (other than one covered by another form), he or she may be provided the Transfer of Care—Request for Information Form for the treating physician to complete. The Transfer of Care—Request for Information Form may also be provided to an Applicant whose responses on the Health History Form indicate that the Applicant may have an unstable medical condition that requires ongoing treatment. The Transfer of Care—Request for Information Form asks the physician to document the diagnosis, current treatment, physical limitations and the likelihood of significant progression of the condition over the next three years. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer assignment and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation (*e.g.,* avoidance of high altitudes or proximity to a hospital) that may be needed to manage the Applicant's medical condition.

- Mental Health Current Evaluation and Treatment Summary Form
  - (a) Estimated number of Applicants/professional—1,221/1,221
  - (b) Frequency of response—one time
  - (c) Estimated average burden per response—105 minutes/60 minutes
  - (d) Estimated total reporting burden—2,137 hours/1,221 hours
  - (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Mental Health Current Evaluation Form will be used when an Applicant reports on the Health History Form a history of certain serious mental health conditions, such as bipolar disorder, schizophrenia, mental health hospitalization, attempted suicide or cutting, or treatments or medications related to these conditions. In these cases, an Applicant will be provided a Mental Health Current Evaluation and Treatment Summary Form for a licensed mental health counselor, psychiatrist or psychologist to complete. The Mental Health Current Evaluation and Treatment Summary Form asks the counselor, psychiatrist or psychologist to document the dates and frequency of therapy sessions, clinical diagnoses, symptoms, course of treatment, psychotropic medications, mental health history, level of functioning, prognosis, risk of exacerbation or recurrence while overseas, recommendations for follow up and any concerns that would prevent the Applicant from completing 27 months of service without unreasonable disruption. A current mental health evaluation might be needed if information on the condition is out-dated or previous reports on the

condition do not provide enough information to adequately assess the current status of the condition. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate mental health support.

- Functional Abilities Evaluation Form
  (a) Estimated number of Applicants/professional—300/300
  (b) Frequency of response—one time
  (c) Estimated average burden per response—90 minutes/45 minutes
  (d) Estimated total reporting burden—390 hours/225 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: When an Applicant reports on the Health History Form a functional ability limitation he or she will be provided this form to determine the type of accommodation and/or placement program support (*e.g.,* proximity to program site, support support devices) that may be needed to manage the Applicant's medical condition. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer assignment and complete a tour of service without unreasonable disruption due to health problems.

- Eating Disorder Treatment Summary Form
  (a) Estimated number of Applicants/physicians—282/282
  (b) Frequency of response—one time
  (c) Estimated average burden per response—105 minutes/60 minutes
  (d) Estimated total reporting burden—494 hours/282 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Eating Disorder Treatment Summary will be used when an Applicant reports a past or current eating disorder diagnosis in the Health History Form. In these cases the Applicant is provided an Eating Disorder Treatment Summary Form for a mental health specialist, preferably with eating disorder training, to complete. The Eating Disorder Treatment Summary Form asks the mental health specialist to document the dates and frequency of therapy sessions, clinical diagnoses, presenting problems and precipitating factors, symptoms, Applicant's weight over the past three years, relevant family history, course of treatment, psychotropic medications, mental health history inclusive of eating disorder behaviors, level of functioning, prognosis, risk of recurrence in a stressful overseas environment, recommendations for follow up, and any concerns that would prevent the Applicant from completing 27 months of service without unreasonable disruption due to the diagnosis. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer assignment and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate mental health support.

- Substance-Related and Addictive Disorders Current Evaluation Form
  (a) Estimated number of Applicants/specialist—373/373
  (b) Frequency of response—one time
  (c) Estimated average burden per response—165 minutes/60 minutes
  (d) Estimated total reporting burden—1,026 hours/373 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Alcohol/Substance Abuse Current Evaluation Form is used when an Applicant reports in the Health History Form a history of substance abuse (*i.e.,* alcohol or drug related problems such as blackouts, daily or heavy drinking patterns or the misuse of illegal or prescription drugs) and that this substance abuse affects the Applicant's daily living or that the Applicant has ongoing symptoms of substance abuse. In these cases, the Applicant is provided an Substance-Related and Addictive Disorders Current Evaluation Form for a substance abuse specialist to complete. The Substance-Related and Addictive Disorders Current Evaluation Form asks the substance abuse specialist to document the history of alcohol/substance abuse, dates and frequency of any therapy sessions, which alcohol/substance abuse assessment tools were administered, mental health diagnoses, psychotropic medications, self harm behavior, current clinical assessment of alcohol/substance use, clinical observations, risk of recurrence in a stressful overseas environment, recommendations for follow up, and any concerns that would prevent the Applicant from completing a tour of service without unreasonable disruption due to the diagnosis. This form will be used as the basis for an individualized determination as to whether the Applicant will, with reasonable accommodation, be able to perform the essential functions of a Peace Corps Volunteer and complete a tour of service without unreasonable disruption due to health problems. This form will also be used to determine the type of accommodation that may be needed, such as placement of the Applicant in a country with appropriate sobriety support or counseling support.

- Mammogram Waiver Form
  (a) Estimated number of Applicants—148
  (b) Frequency of response—one time
  (c) Estimated average burden per response—105 minutes
  (d) Estimated total reporting burden—259 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Mammogram Form is used for all Applicants who have female breasts and will be 50 years of age or older during service who wish to waive routine mammogram screening during service. If an Applicant waives routine mammogram screening during service, the Applicant's physician is asked to complete this form in order to make a general assessment of the Applicant's statistical breast cancer risk and discussed the results with the Applicant including the potential adverse health consequence of foregoing screening mammography.

- Cervical Cancer Screening Form
  (a) Estimated number of Applicants—3,600/3,600
  (b) Frequency of response—one time
  (c) Estimated average burden per response—40 minutes/30 minutes
  (d) Estimated total reporting burden—2,400 hours/1,800 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Cervical Cancer Screening Form is used with all Applicants with a cervix. Prior to medical clearance, female Applicants are required to submit a current cervical cancer screening examination and Pap cytology report based the American Society for Colploscopy and Cervical Pathology (ASCCP) screening time-line for their age and Pap history. This form assists the Peace Corps in determining whether an Applicant with mildly abnormal Pap history will need to be

placed in a country with appropriate support.

- Colon Cancer Screening Form
  (a) Estimated number of Applicants—575
  (b) Frequency of response—one time
  (c) Estimated average burden per response—60 minutes–165 minutes
  (d) Estimated total reporting burden—575 hours–1,581 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Colon Cancer Screening Form is used with all Applicants who are 50 years of age or older to provide the Peace Corps with the results of the Applicant's latest colon cancer screening. Any testing deemed appropriate by the American Cancer Society is accepted. The Peace Corps uses the information in the Colon Cancer Screening Form to determine if the Applicant currently has colon cancer. Additional instructions are included pertaining to abnormal test results.

- ECG Form
  (a) Estimated number of Applicants/physicians—575/575
  (b) Frequency of response—one time
  (c) Estimated average burden per response—25 minutes/15 minutes
  (d) Estimated total reporting burden—240 hours/144 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The ECG/EKG Form is used with all Applicants who are 50 years of age or older to provide the Peace Corps with the results of an electrocardiogram. The Peace Corps uses the information in the electrocardiogram to assess whether the Applicant has any cardiac abnormalities that might affect the Applicant's service. Additional instructions are included pertaining to abnormal test results. The electrocardiogram is performed as part of the Applicant's physical examination.

- Reactive Tuberculin Test Evaluation Form
  (a) Estimated number of Applicants/physicians—392/392
  (b) Frequency of response—one time
  (c) Estimated average burden per response—75–105 minutes/30 minutes
  (d) Estimated total reporting burden—490–686 hours/196 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Reactive Tuberculin Test Evaluation Form is used when an Applicant reports a history of treatment for active tuberculosis or a history of a positive tuberculosis (TB) test on their Health History Form or if a positive TB test result is noted as a component of the Applicant's physical examination findings. In these cases, the Applicant is provided a Reactive Tuberculin Test Evaluation Form for the treating physician to complete. The treating physician is asked to document the type and date of a current TB test, TB test history, diagnostic tests if indicated, treatment history, risk assessment for developing active TB, current TB symptoms, and recommendations for further evaluation and treatment. In the case of a positive result on the TB test, a chest X-ray may be required, along with treatment for latent TB.

- Insulin Dependent Supplemental Documentation Form
  (a) Estimated number of Applicants/physicians—14/14
  (b) Frequency of response—one time
  (c) Estimated average burden per response—70 minutes/60 minutes
  (d) Estimated total reporting burden—16 hours/14 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Insulin Dependent Supplemental Documentation Form is used with Applicants who have reported on the Health History Form that they have insulin dependent diabetes. In these cases, the Applicant is provided an Insulin Dependent Supplemental Documentation Form for the treating physician to complete. The Insulin Dependent Supplemental Documentation Form asks the treating physician to document that he or she has discussed with the Applicant medication (insulin) management, including whether an insulin pump is required, as well as the care and maintenance of all required diabetes related monitors and equipment. This form assists the Peace Corps in determining whether the Applicant will be in need of insulin storage while in service and, if so, will assist the Peace Corps in determining an appropriate placement for the Applicant.

- Prescription for Eyeglasses Form
  (a) Estimated number of Applicants/physicians—3,293/3,293
  (b) Frequency of response—one time
  (c) Estimated average burden per response—60 minutes/15 minutes
  (d) Estimated total reporting burden—3,293 hours/824 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Prescription for Eyeglasses is used with Applicants who have reported on the Health History Form that they use corrective lenses or otherwise have uncorrected vision that is worse than 20/40. In these cases, Applicants are provided a Prescription for Eyeglasses Form for their prescriber to indicate eyeglasses frame measurements, lens instructions, type of lens, gross vision and any special instructions. This form is used in order to enable the Peace Corps to obtain replacement eyeglasses for a Volunteer during service.

- Required Peace Corps Immunizations Form
  (a) Estimated number of Applicants/physicians—5,600
  (b) Frequency of response—one time
  (c) Estimated average burden per response—60 minutes
  (d) Estimated total reporting burden—5,600 hours
  (e) Estimated annual cost to respondents—Indeterminate

General Description of Collection: The Required Peace Corps Immunizations Form is used to informed Applicants of the specific vaccines and/or documented proof of immunity required for medical clearance for the specific country of service. The form advises the Applicant that all other Center for Disease Control (CDC) recommended vaccinations will be administered after arrival in-country. This form assists the Peace Corps with establishing a baseline of the Applicants immunization history and prepare for any additional vaccines recommended for country of service.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity 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 automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on November 3, 2020.

Virginia Burke,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2020–24780 Filed 11–6–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90319; File No. SR–CBOE–2020–014]

Self-Regulatory Organizations; Cboe Exchange, Inc; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt the Delta-Adjusted at Close Order Instruction

November 3, 2020.

I. Introduction

On February 18, 2020, Cboe Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to introduce the Delta-Adjusted at Close (''DAC'') Order Instruction on the Exchange. The proposed rule change was published for comment in the **Federal Register** on March 9, 2020.[3] On April 13, 2020, 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 the proposed rule change should be disapproved.[4] On May 12, 2020, the Exchange submitted Amendment No. 1 to the proposed rule change.[5] On June 3, 2020, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[6] On September 3, 2020, the Commission designated a longer period for Commission action on proceedings to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[7] The Commission has received one comment on the proposed rule change.[8] This order approves the proposed rule change, as modified by Amendment No. 1.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 88312 (March 3, 2020), 85 FR 13686 (''Notice'').

[4] *See* Securities Exchange Act Release No. 88622, 85 FR 21490 (April 17, 2020).

[5] *See https://www.sec.gov/comments/sr-cboe-2020-014/srcboe2020014-7180918-216787.pdf.*

[6] *See* Securities Exchange Act Release No. 88997, 85 FR 35351 (June 9, 2020) (''Order Instituting Proceedings'').

[7] *See* Securities Exchange Act Release No. 89765, 85 FR 55905 (September 10, 2020).

[8] *See* Letter from Kurt Eckert, Partner, Wolverine Execution Services, LLC, to Vanessa Countryman, Secretary, Commission, dated June 24, 2020 (''WEX Letter''), *available at https://www.sec.gov/comments/sr-cboe-2020-014/srcboe2020014-7343517-218670.pdf.*

II. Summary of the Proposed Rule Change, as Modified by Amendment No. 1

A. Proposed DAC Order Instruction—Generally

As modified by Amendment No. 1, the Exchange proposes to implement a DAC order instruction that a User [9] may only apply to an order upon System [10] entry (including each leg of a complex order) for an option on an Exchange Traded Product (''ETP'') or index for execution in a FLEX electronic or open outcry auction.[11] A DAC order could execute throughout the trading day. After the close of trading and upon receipt of the official closing price or value for the underlying ETP or index from the primary listing exchange or index provider, as applicable, the System would adjust the original execution price of the order based on a pre-determined delta value applied to the change in the underlying reference price between the time of execution and the market close.

The Exchange states that there can be substantial activity in an underlying near the market close that may create wider spreads and increased price volatility in the underlying, which may attract additional trading activity from market participants seeking arbitrage opportunities and further increase volatility. This activity near market close makes it difficult to execute FLEX option orders based on the exact closing price or value of the underlying (''execution risk'').[12] The Exchange states that the DAC order is designed to allow Users to incorporate into the pricing of their FLEX options the closing price or value of the underlying ETP or index on the transaction date based on how much the price or value changed during the trading day. The Exchange also represents that DAC orders will have unique message characteristics such that contra-side interest will be aware of, and may choose whether to interact with, the DAC order. Finally, the Exchange believes that the DAC order would be particularly useful for investors that participate in defined outcome strategies, including defined-outcome exchange-traded funds (''ETFs''), other managed funds, unit investment trusts (''UITs''), index funds, structured annuities, and other such funds or instruments that are indexed.

B. DAC Orders and FLEX Options

As stated above, the use of the DAC order instruction is limited to the trading of an option on an ETP or index for execution in a FLEX electronic or open outcry auction, and would be handled and executed in the same manner as any other FLEX option order pursuant to the applicable FLEX auction rules, including pricing, priority, and allocation rules.[13] Specifically, pursuant to Rules 5.72, 5.73, and 5.74, FLEX Orders (including proposed DAC orders) may only execute in a FLEX electronic or open outcry auction which would include the FLEX Automated Improvement Auction,[14] the FLEX Solicitation Auction Mechanism or,[15] a FLEX order submitted for manual handling in an open outcry auction on the Exchange's trading floor.[16] Pursuant to proposed Rule 5.33(b)(5), a DAC order instruction may be used in conjunction with complex orders that are submitted for execution in a FLEX complex electronic or open outcry auctions pursuant to proposed Rule 5.72.

The DAC order instruction may not be used with all FLEX orders. Specifically, proposed Rule 5.70(a)(2) sets forth that a User may not apply the DAC order instruction to a FLEX order for a FLEX option series with an exercise price formatted as a percentage of the closing value of the underlying on the trade date. In other words, the exercise price of a DAC order must be expressed as a fixed price in dollars and decimals because otherwise, according to the Exchange, the formatting would not be compatible with the DAC order instruction. Proposed Rule 5.70(a)(2) also prohibits the use of the DAC order instruction with FLEX Option series that are Asian or Cliquet-settled because DAC orders would be based on the movement of the underlying on the transaction date but the prices for Asian or Cliquet-settled options are determined by averaging a pre-set number of closing index values or summing the monthly returns,

[9] The term ''User'' means any TPH or Sponsored User who is authorized to obtain access to the System pursuant to Rule 5.5. *See* Rule 1.1.

[10] The term ''System'' means the Exchange's hybrid trading platform that integrates electronic and open outcry trading of option contracts on the Exchange, and includes any connectivity to the foregoing trading platform that is administered by or on behalf of the Exchange, such as a communications hub. *See* Rule 1.1.

[11] For a more detailed description of the proposed rule change, as modified by Amendment No. 1, *see* Order Instituting Proceedings, *supra* note 6. *See also supra* note 5.

[12] *See* Order Instituting Proceedings, *supra* note 6, at 35352.

[13] *See* Rules 5.72(b), (c), and (d).

[14] *See* Rule 5.73.

[15] *See* Rule 5.74.

[16] *See* Rule 5.72(d).

respectively, on specified monthly observation dates.[17]

C. Delta and Reference Prices

As stated above, the original execution price of a DAC order that executes during the trading day would be delta-adjusted at the market close upon receipt of the official closing price or value for the underlying ETP or index from the primary listing exchange or index provider, as applicable.[18] Delta is the measure of the change in the option price as it relates to a change in the price of the underlying security or value of the underlying index, as applicable. For example, an option with a 50 delta (which is generally represented as 0.50) would result in the option moving $0.50 per $1.00 move in the underlying (*i.e.,* price move in the underlying × delta value = anticipated price move in the option). The delta changes as a result from the passage of time and changes to the price or value of the underlying stock or index changes, and provide Users with an estimate of how an option reacts to movement, in either direction, of the underlying. For example, call option deltas are positive (ranging from 0 to 1), because as the underlying increases in price so does a call option. Conversely, put option deltas are negative (ranging from –1 to 0), because as the underlying increases in price the put option decreases in price. Specifically, the delta-adjusted execution price would equal the original execution price plus the delta value times the difference between the official closing price or value of the underlying on the transaction date and the reference price or index value of the underlying (''reference price'').

A User entering a DAC order for a FLEX electronic auction must designate a delta value and may designate a reference price.[19] If no reference price is designated, the System would include the price or value, as applicable, of the underlying at the time of order entry as the reference price.[20] A User entering a DAC order for a FLEX open outcry auction may, but is not required to, designate a delta value and/or a reference price.[21] During the FLEX open outcry auction, the User designated delta value or reference price may differ from the final terms of the order because in-crowd market participants[22] can negotiate the final delta value and/or reference price.[23] A User entering a complex order with a DAC order instruction into a FLEX electronic auction is required to designate a delta value for each leg of the complex order pursuant to proposed Rule 5.33(b)(5)).[24]

User-designated reference prices will be subject to a reasonability check to determine if the DAC order would be cancelled or rejected by the System for being more than an Exchange-determined amount away from the underlying price or value at the time of submission.[25] In addition, if a DAC order is submitted without a reference price, the System would automatically input a reference price equal to the price or value of the underlying at the time of order entry.[26] The ultimate delta value and reference price would be reflected in the final terms of the execution.[27]

The Exchange represents that its electronic and open outcry FLEX auctions currently last between three seconds to five minutes as designated by the Submitting/Initiating FLEX Trader.[28] Accordingly, to the extent a DAC order executes in a FLEX auction, it would do so within the three second to five minute timeframe which should limit the impact of time on the delta and reference price and help investors meet their goal of limiting downside risk while still being able to participate in any upward movement in the market.

D. Time-in-Force

Proposed Rule 5.6(c) sets forth that a DAC order submitted for execution in open outcry may only have a Time-in-Force of Day.[29] If not executed, an order with a Time-in-force of Day would expire at Regular Trading Hours (''RTH'') market close. Proposed Rule 5.6(c) also provides that a User may not designate a DAC order as All Sessions (*i.e.,* eligible for RTH and Global Trading Hours),[30] as the adjustment calculation for DAC orders is linked to the RTH market close for the underlying securities and indexes.[31] The Exchange explained that the proposed Time-in-Force of Day requirement for DAC orders submitted for execution in open outcry correlates with the need for any execution to occur within a limited timeframe after the order's entry in order to achieve the result desired by the broker's customer.[32]

E. Trade Reporting

When a DAC order is executed, the time of the execution, original execution price, the reference price and delta value will be provided to all transaction parties on all fill reports (*i.e.,* an ''unadjusted DAC trade'').[33] Unadjusted DAC trade information will also be sent to the Options Clearing Corporation (''OCC'') and disseminated to Options Price Reporting Agency (''OPRA'').[34] Like all FLEX Orders, DAC order trade information will be reported via a text message to OPRA[35] reflecting the (1) execution of a DAC order, (2) delta, and (3) reference price.[36] Like all complex orders, the individual legs of DAC complex orders would be reported with an identifier to indicate that they are part of a complex order.[37] At the market close, when the execution price is delta-adjusted, all transactions parties will be sent fill restatements. Matched trades with the delta-adjusted price will also be sent to the OCC and OPRA once the restatement process is complete. The prior unadjusted DAC trade report that was sent to the OCC and disseminated to OPRA will be cancelled and replaced with a trade report reflecting the delta-adjusted execution price. The remaining information (*i.e.,* time of the execution, delta, and reference price) would be unchanged.[38] A new DAC order text message would be disseminated to OPRA with the same information included in the original text plus the closing price. The Exchange states that

[17] *See* Rule 4.21(b)(5)(B).

[18] According to the Exchange, like the execution price of any option, a delta-adjusted price may never be zero or negative and the System would instead set the delta-adjusted price to the minimum permissible increment if such a calculation were to occur. *See* Order Instituting Proceedings, *supra* note 6, at 35353.

[19] *See* proposed Rules 5.6(c) and 5.33(b)(5).

[20] *See id.*

[21] *See* proposed Rules 5.6(c) and 5.33(b)(5).

[22] The Exchange states that in-crowd participants currently have delta values built into their own analytics and pricing tools and that there is generally only a slight difference of values across participants. *See* Order Instituting Proceedings, *supra* note 6, at 35353, n. 25.

[23] *See id.*

[24] *See* proposed Rule 5.72(b)(2)(A).

[25] The System will use the most recent last sale (or disseminated index value) as the reference price. *See* proposed Rule 5.34(c)(12).

[26] *See* proposed Rules 5.6(c) and 5.33(b)(5).

[27] *See id.* The Exchange provided examples to demonstrate how the System would apply the delta adjustment formula to DAC orders a t the market close. *See* Order Instituting Proceedings, *supra* note 6, at 35353–54.

[28] *See* Rules 5.72(c), 5.73(c)(3) and 5.74(c)(3).

[29] The Exchange notes that electronically submitted DAC orders will be submitted through the electronic auctions, and either executed or cancelled upon the conclusion of an auction, making an instruction regarding the time the System will hold an order unnecessary. Therefore, the Exchange believes that a requirement to apply a Time-in-Force of Day is not necessary for electronic DAC orders.

[30] *See* Rule 1.1.

[31] *See* proposed Rules 5.6(c) and 5.33(b)(5).

[32] *See* Order Instituting Proceedings, *supra* note 6, at 35354–55.

[33] *See id.*

[34] *See id.*

[35] *See id.*

[36] *See id.*

[37] *See id.*

[38] The Exchange notes that this restatement process is the same for an order that has been adjusted or nullified and subsequently restated pursuant to the Exchange's obvious error rules. *See* Rule 6.5.

OCC and OPRA are aware of, and deem acceptable, this proposed restatement process.[39]

F. System Capacity and Surveillance

The Exchange represents that it believes: (1) The Exchange and OPRA have the necessary systems capacity to handle any additional order traffic, and the associated restatements, that may result from the use of DAC orders, and (2) its surveillance program is adequately robust to monitor orders with delta-adjusted pricing, and (3) the DAC order will not have any impact on pricing or price discovery at or near the market close.[40]

III Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[41] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[42] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange proposes to introduce the DAC order instruction for use with both simple and complex orders for FLEX options on ETPs and indexes in electronic or open outcry auctions. The DAC order would execute during the trading day and the original execution price would be adjusted after receipt of the official closing price/value for the underlying ETP or index from the primary listing exchange or index provider, as applicable, based on a delta value applied to the change in the underlying reference price between the time of execution and the market close. The Exchange states that the introduction of the DAC order instruction will allow market participants to incorporate into the pricing of their FLEX options the closing price of the underlying ETP or index on the transaction date, based on the amount in which the price or value of the underlying ETP or index changes intraday. The Exchange also states that the DAC order will be useful to investors that engage in defined-outcome strategies and that certain market participants, managed funds in particular, already use similar strategies at the market close.

The Commission received one comment letter supporting the Exchange's proposal.[43] The commenter agrees with the Exchange that there may be dislocations in the closing price of a FLEX option and its execution price,[44] and that the DAC order would eliminate such dislocations while limiting downside risk and allowing users to incorporate any upside market moves that may occur following the execution of the order up to the market close.[45] The commenter also believes that the DAC order will improve the efficiency of the options market.[46]

The Commission believes that the DAC order instruction is designed to remove impediments to and perfect the mechanism of a free and open market by allowing market participants to more effectively incorporate the closing price of the underlying ETP or index into the execution price of the FLEX option, which should facilitate the ability of market participants to execute certain investment strategies. Specifically, as the Exchange notes, the DAC order instruction would allow FLEX option orders to be executed anytime during the trading day, eliminating execution risk near the market close and thereby realizing the objective of pricing based on the exact underlying closing prices. The Commission believes that the proposal is designed to protect investors by providing them with a mechanism designed to ensure FLEX option pricing certainty based on the closing price of the underlying ETP or index and to eliminate execution risk near the market close, which should effectively implement their investment strategies. The Commission agrees with the Exchange that, at this time, it is appropriate to limit the use of the DAC order instruction to FLEX options on ETPs and indexes as the stated goal of the DAC order instruction is to assist investors that participate in defined-outcome investment strategies, including defined-outcome ETFs, other managed funds, UITs, index funds, structured annuities, and other such funds or instruments that are indexed.

The Commission believes that DAC orders are designed promote just and equitable principles of trade as their operation should be transparent to market participants and the implementation of DAC orders should not raise any new or novel order entry, allocation, and execution processes. For instance, DAC orders will be entered and processed pursuant to the existing FLEX rules like any other order that is submitted into a FLEX electronic or open outcry auction.[47] The Commission also believes that the proposed delta adjustment of DAC orders is designed to promote just and equitable principles of trade and to remove impediments to and perfect the mechanism of a free and open market because it is consistent with the general manner in which deltas function. The Exchange has designed the proposal to limit the period between entry and execution of a DAC order. Because the Exchange's electronic and open outcry FLEX auctions currently last between three seconds to five minutes, DAC orders should generally execute within a timeframe that limits the impact of the passage of time on the delta and reference price. Taken together, the Commission believes that the DAC order is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market, and to protect investors by providing a mechanism to effectively implement certain investment strategies to market participants that should have familiarity with the design and strategy of the order type.

Finally, the Exchange represents that: (1) DAC orders will have unique message characteristics that will indicate to contra-side interest its status as a DAC order which will allow market participants to choose whether to interact with DAC orders, (2) the OCC and OPRA are able to accommodate the DAC restatement process, (3) the Exchange and OPRA have the necessary systems capacity to handle additional order traffic, and the associated restatements, that may result from the use of DAC orders, (4) the Exchange's surveillance program will monitor the pricing of DAC orders, and (5) DAC orders should not have any impact on pricing or price discovery in the underlying products at or near the market close.

Accordingly, for the foregoing reasons, the Commission believes that this proposed rule change, as modified

[39] *See* Order Instituting Proceedings, *supra* note 6, at 35355.

[40] *See id.*

[41] 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).

[42] 15 U.S.C. 78f(b)(5).

[43] *See* WEX Letter, *supra* note 8.

[44] *See id.* at 1.

[45] *See id.*

[46] *See id.* at 2.

[47] *See* Rules 5.72(d).

by Amendment No. 1, is consistent with the Exchange Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[48] that the proposed rule change (SR–CBOE–2020–014), as modified by Amendment No.1, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[49]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24784 Filed 11–6–20; 8:45 am]

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[48] 15 U.S.C. 78s(b)(2).

[49] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–325, OMB Control No. 3235–0385]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 15g–9

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Section 15(c)(2) of the Securities Exchange Act of 1934 (15 U.S. C. 78a *et seq.*) (the ''Exchange Act'') authorizes the Commission to promulgate rules that prescribe means reasonably designed to prevent fraudulent, deceptive, or manipulative practices in connection with over-the-counter (''OTC'') securities transactions. Pursuant to this authority, the Commission in 1989 adopted Rule 15a&6, which was subsequently redesignated as Rule 15g–9, 17 CFR 240.15g–9 (the ''Rule''). The Rule requires broker-dealers to produce a written suitability determination for, and to obtain a written customer agreement to, certain recommended transactions in penny stocks that are not registered on a national securities exchange, and whose issuers do not meet certain minimum financial standards. The Rule is intended to prevent the indiscriminate use by broker-dealers of fraudulent, high pressure telephone sales campaigns to sell penny stocks to unsophisticated customers.

The Commission staff estimates that there are approximately 182 broker-dealers subject to the Rule. The burden of the Rule on a respondent varies widely depending on the frequency with which new customers are solicited. On the average for all respondents, the staff has estimated that respondents process three new customers per week, or approximately 156 new customer suitability determinations per year. We also estimate that a broker-dealer would expend approximately one-half hour per new customer in obtaining, reviewing, and processing (including transmitting to the customer) the information required by Rule 15g–9, and each respondent would consequently spend 78 hours annually (156 customers × .5 hours) obtaining the information required in the rule. We determined, based on the estimate of 182 broker-dealer respondents, that the current annual burden of Rule 15g–9 is 14,196 hours (182 respondents × 78 hours).

The broker-dealer must keep the written suitability determination and customer agreement required by the Rule for at least three years. Completing the suitability determination and obtaining the customer agreement in writing is mandatory for broker-dealers who effect transactions in penny stocks and do not qualify for an exemption, but does not involve the collection of confidential information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 4, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24838 Filed 11–6–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90330; File No. SR–NYSE–2020–73]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend the Exchange's Co-Location Services To Establish Procedures for the Allocation of Cabinets to Its Co-Located Users

November 3, 2020.

On September 2, 2020, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish procedures as part of the Exchange's co-location rules to allocate cabinets to its co-located users in situations where the Exchange cannot satisfy the user demand for cabinets. The proposed rule change was published for comment in the **Federal Register** on September 21, 2020.[3] The Commission received no comments on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 5, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89879 (September 15, 2020), 85 FR 59361 (SR–NYSE–2020–73).

[4] 15 U.S.C. 78s(b)(2).

which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates December 20, 2020, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSE–2020–73).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24792 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33–10885; 34–90338; File No. 265–28]

Investor Advisory Committee Meeting

AGENCY: Securities and Exchange Commission.

ACTION: Notice of public meeting.

SUMMARY: The Securities and Exchange Commission Investor Advisory Committee, established pursuant to Section 911 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, is providing notice that it will hold a public meeting. The public is invited to submit written statements to the Committee.

DATES: The meeting will be held on Thursday, December 3, 2020 from 10:00 a.m. until 4:00 p.m. (ET). Written statements should be received on or before December 3, 2020.

ADDRESSES: The meeting will be conducted by remote means and/or at the Commission's headquarters, 100 F St NE, Washington, DC 20549. The meeting will be webcast on the Commission's website at *www.sec.gov.* Written statements may be submitted by any of the following methods:

Electronic Statements

- Use the Commission's internet submission form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email message to *rules-comments@sec.gov.* Please include File No. 265–28 on the subject line; or

Paper Statements

- Send paper statements to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549–1090.

All submissions should refer to File No. 265–28. This file number should be included on the subject line if email is used. To help us process and review your statement more efficiently, please use only one method.

Statements also will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Room 1503, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All statements 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.

FOR FURTHER INFORMATION CONTACT: Marc Oorloff Sharma, Chief Counsel, Office of the Investor Advocate, at (202) 551–3302, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public, except during that portion of the meeting reserved for an administrative work session during lunch. Persons needing special accommodations to take part because of a disability should notify the contact person listed in the section above entitled **FOR FURTHER INFORMATION CONTACT**. The agenda for the meeting includes: welcome remarks; announcement of results of officers election; approval of previous meeting minutes; a panel discussion regarding corporate disclosure during COVID–19; a panel discussion regarding COVID–19 implications for next proxy season; subcommittee reports; and a non-public administrative session.

Dated: November 4, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–24846 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90326; File No. SR–NYSEArca–2020–82]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend the Exchange's Co-Location Services To Establish Procedures for the Allocation of Cabinets to Its Co-Located Users

November 3, 2020.

On September 2, 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 establish procedures as part of the Exchange's co-location rules to allocate cabinets to its co-located users in situations where the Exchange cannot satisfy the user demand for cabinets. The proposed rule change was published for comment in the **Federal Register** on September 22, 2020.[3] The Commission received no comments on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 6, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates December 21, 2020, as the date by which the Commission shall either approve or disapprove, or

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89883 (September 16, 2020), 85 FR 59568 (SR–NYSEArca–2020–82).

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2020–82).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24788 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90323; File No. SR–NYSEArca–2020–94]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To List and Trade Shares of the AdvisorShares Q Portfolio Blended Allocation ETF and AdvisorShares Q Dynamic Growth ETF Under Rule 8.900–E

November 3, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 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, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of the following under Rule 8.900–E (Managed Portfolio Shares): AdvisorShares Q Portfolio Blended Allocation ETF and AdvisorShares Q Dynamic Growth ETF. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

NYSE Arca Rule 8.900–E permits the listing and trading, or trading pursuant to unlisted trading privileges (''UTP''), of Managed Portfolio Shares, which are securities issued by an actively managed open-end investment management company.[4] 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. Therefore, the Exchange is submitting this proposal in order to list and trade Managed Portfolio Shares of the AdvisorShares Q Portfolio Blended Allocation ETF and AdvisorShares Q Dynamic Growth ETF (each a ''Fund'' and, collectively, the ''Funds'') under Rule 8.900–E.

Description of the Funds and the Trust

The shares of each Fund (the ''Shares'') will be issued by the AdvisorShares Trust (the ''Trust''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company.[5] The investment adviser to each Fund will be AdvisorShares Investments, LLC (the ''Adviser''). The investment sub-advisor to each Fund will be ThinkBetter, LLC. Foreside Fund Services, LLC (the ''Distributor'') will serve as the distributor of each of the Funds' Shares. All statements and representations made in this filing 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 Rule 8.900–E(b)(1).

Rule 8.900–E(b)(4) provides that, if the investment adviser to the Investment Company issuing Managed Portfolio Shares is registered as a broker-dealer or is affiliated with a broker-dealer, such investment adviser will erect and maintain a ''fire wall'' between the investment adviser and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition of and/or changes to such Investment Company portfolio and/or the Creation Basket.[6] Any person related to the investment adviser or Investment Company who makes decisions pertaining to the Investment Company's portfolio composition or has access to information regarding the Investment Company's portfolio composition or changes thereto or the Creation Basket must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the applicable Investment

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Rule 8.900–E(c)(1) provides that the term ''Managed Portfolio Share'' means a security that (a) represents an interest in an investment company registered under the Investment Company Act of 1940 (''Investment Company'') 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; (b) is issued in a Creation Unit, or multiples thereof, in return for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value and delivered to the Authorized Participant (as defined in the Investment Company's Form N–1A filed with the Commission) through a Confidential Account; (c) when aggregated into a Redemption Unit, or multiples thereof, may be redeemed for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value delivered to the Confidential Account for the benefit of the Authorized Participant; and (d) the portfolio holdings for which are disclosed within at least 60 days following the end of every fiscal quarter.

[5] The Trust is registered under the 1940 Act. On September 11, 2020, the Trust filed a registration statement on Form N–1A under the Securities Act of 1933 (the ''1933 Act'') and the 1940 Act for the Funds (File Nos. 333–157876 and 811–22110) (''Registration Statement''). The description of the operation of the Trust and the Funds herein is based, in part, on the Registration Statement. The Trust has filed an application for an order under Section 6(c) of the 1940 Act for exemptions from various provisions of the 1940 Act and rules thereunder (the ''Exemptive Application'') (File No. 812–15146). The Exchange will not commence trading in Shares of the Funds until the Commission has issued an order granting the exemptions requested in the Exemptive Application.

[6] Rule 8.900–E(c)(5) provides that the term ''Creation Basket'' means, on any given business day, the names and quantities of the specified instruments (and/or an amount of cash) that are required for an AP Representative to deposit in-kind on behalf of an Authorized Participant in exchange for a Creation Unit and the names and quantities of the specified instruments (and/or an amount of cash) that will be transferred in-kind to an AP Representative on behalf of an Authorized Participant in exchange for a Redemption Unit, which will be identical and will be transmitted to each AP Representative before the commencement of trading.

Company portfolio or changes thereto or the Creation Basket.

Rule 8.900–E(b)(4) is similar to Commentary .03(a)(i) and (iii) to Rule 5.2–E(j)(3); however, Commentary .03(a) in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds.[7] Rule 8.900–E(b)(4) is also similar to Commentary .06 to Rule 8.600–E related to Managed Fund Shares, except that Rule 8.900–E(b)(4) relates to establishment and maintenance of a ''fire wall'' between the investment adviser and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to an Investment Company's portfolio and Creation Basket, and not just to the underlying portfolio, as is the case with Managed Fund Shares. The Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer. The Adviser has implemented and will maintain a ''fire wall'' with respect to such broker-dealer affiliate regarding access to information concerning the composition of and/or changes to a Fund's portfolio and/or Creation Basket.

In the event (a) the Adviser or any sub-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, it 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. 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 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.

Further, Rule 8.900–E(b)(5) requires that any person or entity, including an AP Representative, custodian, Reporting Authority, distributor, or administrator, who has access to non-public information regarding the Investment Company's portfolio composition or changes thereto or the Creation Basket, must be subject to procedures reasonably designed to prevent the use and dissemination of material non-public information regarding the applicable Investment Company portfolio or changes thereto or the Creation Basket. Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity will erect and 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 Investment Company portfolio or Creation Basket.

Description of the Funds [8]

Each Fund's holdings will conform to the permissible investments as set forth in the Exemptive Application and the holdings will be consistent with all requirements in the Exemptive Application.[9]

AdvisorShares Q Portfolio Blended Allocation ETF

The Fund is an actively managed ETF that is primarily a ''fund of funds.'' The Fund's investment objective is to seek to maximize total return over the long-term. The Fund will invest in ETFs representing all asset classes, including, but not limited to, treasury bonds, municipal bonds, investment grade corporate bonds, high-yield U.S. corporate bonds, U.S. and foreign equities, and commodities.

AdvisorShares Q Dynamic Growth ETF

The Fund is an actively managed ETF that is primarily a ''fund of funds.'' The Fund seeks to achieve long-term growth. The Fund will invest in ETFs representing all asset classes, including, but not limited to, treasury bonds, municipal bonds, investment grade corporate bonds, high-yield U.S. corporate bonds, U.S. and foreign equities, commodities, and volatility products.

Investment Restrictions

Each Fund's holdings will be consistent with all requirements described in the Exemptive Application.[10]

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 investment objective.

Creations and Redemptions of Shares

Creations and redemptions of Shares will take place as described in Rule 8.900–E. Specifically, in connection with the creation and redemption of Creation Units [11] and Redemption Units,[12] the delivery or receipt of any portfolio securities in-kind will be required to be effected through a separate confidential brokerage account (a ''Confidential Account'').[13]

[7] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel will be subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violations, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above. The Funds will also be required to comply with Exchange rules relating to disclosure, including Rule 5.3–E(i).

[8] The Exchange represents that, for initial and/or continued listing, each Fund will be in compliance with Rule 10A–3 under the Act. *See* 17 CFR 240.10A–3.

[9] Pursuant to the Exemptive Application, the only permissible investments for a Fund are the following that trade on a U.S. exchange contemporaneously with the Funds' Shares: 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).

[10] *See id.*

[11] Rule 8.900–E(c)(6) provides that the term ''Creation Unit'' means a specified minimum number of Managed Portfolio Shares issued by an Investment Company at the request of an Authorized Participant in return for a designated portfolio of instruments and/or cash.

[12] Rule 8.900–E(c)(7) provides that the term ''Redemption Unit'' means a specified minimum number of Managed Portfolio Shares that may be redeemed to an Investment Company at the request of an Authorized Participant in return for a portfolio of instruments and/or cash.

[13] Rule 8.900–E(c)(4) provides that the term ''Confidential Account'' means an account owned by an Authorized Participant and held with an AP Representative on behalf of the Authorized Participant. The account will be established and governed by contractual agreement between the AP Representative and the Authorized Participant

Continued

Authorized Participants (''AP''), as defined in the applicable Form N–1A filed with the Commission, will sign an agreement with an AP Representative [14] establishing the Confidential Account for the benefit of the AP. AP Representatives will be broker-dealers. An AP must be a Depository Trust Company Participant that has executed an authorized participant agreement (''Participant Agreement'') with the Distributor with respect to the creation and redemption of Creation Units and Redemption Units and formed a Confidential Account for its benefit in accordance with the terms of the Participant Agreement. For purposes of creations or redemptions, all transactions will be effected through the respective AP's Confidential Account, for the benefit of the AP, without disclosing the identity of such securities to the AP.

Each AP Representative will be given, before the commencement of trading each Business Day (as defined below), the Creation Basket (as described below) for that day. This information will permit an AP that has established a Confidential Account with an AP Representative to instruct the AP Representative to buy and sell positions in the portfolio securities to permit creation and redemption of Creation Units and Redemption Units. Shares of each Fund will be issued and redeemed in Creation Units and Redemption Units, the size of which will be specified in the Registration Statement. The size of Creation Units and Redemption Units is subject to change. The Funds will offer and redeem Creation Units and Redemption Units on a continuous basis at the net asset value (''NAV'') per Share next determined after receipt of an order in proper form. The NAV per Share of each Fund will be determined as of the close of regular trading on the Exchange on each day that the Exchange is open (a ''Business Day''). The Funds will sell and redeem Creation Units and Redemption Units only on Business Days.

In order to keep costs low and permit each Fund to be as fully invested as possible, Shares will be purchased and redeemed in Creation Units and Redemption Units and generally on an in-kind basis. Accordingly, except where the purchase or redemption will include cash under the circumstances described in the Exemptive Application, APs will be required to purchase Creation Units by making an in-kind deposit of a designated portfolio of securities (''Deposit Securities''), and APs redeeming their Shares will receive an in-kind transfer of a designated portfolio of securities (''Redemption Securities'') through the AP Representative in their Confidential Account.[15] On any given Business Day, the names and quantities of the instruments that constitute the Deposit Securities and the names and quantities of the instruments that constitute the Redemption Securities will be identical, and these instruments may be referred to, in the case of either a purchase or a redemption, as the ''Creation Basket.''

Placement of Purchase Orders

Each Fund will issue Shares through the Distributor on a continuous basis at NAV. The Exchange represents that the issuance of Shares will operate in a manner substantially similar to that of other ETFs. Each Fund will issue Shares only at the NAV per Share next determined after an order in proper form is received.

The Distributor will furnish acknowledgements to those placing such orders that the orders have been accepted, but the Distributor may reject any order which is not submitted in proper form, as described in each Fund's prospectus or Statement of Additional Information (''SAI''). The NAV of each Fund is expected to be determined once each Business Day as of the close of the regular trading session on the NYSE (ordinarily 4:00 p.m. E.T.) (the ''Valuation Time''). To initiate a purchase of Shares, an AP must submit to the Distributor an irrevocable order to purchase such Shares after the most recent prior Valuation Time. In purchasing the necessary securities, the AP Representative will use methods, such as breaking the transaction into multiple transactions and transacting in multiple marketplaces, to avoid revealing the composition of the Creation Basket.

Generally, all orders to purchase Creation Units must be received by the Distributor no later than 3:00 p.m. E.T. (''Order Cut-Off Time'') on the date such order is placed (''Transmittal Date'') in order for the purchaser to receive the NAV per Share determined on the Transmittal Date. As with all existing ETFs, if there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Creation Basket exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the ''Balancing Amount'').

Purchases of Shares will be settled in-kind and/or cash for an amount equal to the applicable NAV per Share purchased plus applicable transaction fees.[16] Other than the Balancing Amount, the Fund will substitute cash only under exceptional circumstances and as set forth under the Fund's policies and procedures governing the composition of Creation Baskets.

Authorized Participant Redemption

The Shares may be redeemed to a Fund in Redemption Unit size or multiples thereof as described below. Redemption orders of Redemption Units must be placed by or through an AP (''AP Redemption Order'') in proper form. Redemption Units of a Fund will be redeemable at their NAV per Share next determined after receipt of a request for redemption by the Trust in the manner specified below before the Order Cut-Off Time. To initiate an AP Redemption Order, an AP must submit to the Distributor an irrevocable order to redeem such Redemption Unit no later than the Order Cut-Off Time on the Transmittal Date. A transaction fee may be imposed to offset costs associated with redemption orders.

In the case of a redemption, the AP would enter into an irrevocable redemption order, and then the applicable Fund would instruct its custodian to deliver the Redemption Securities to the appropriate Confidential Account. The Authorized Participant would direct the AP Representative on when that day to liquidate those securities. As with the purchase of securities, the AP Representative will use methods, such as breaking the transaction into multiple transactions and transacting in multiple

solely for the purposes of creation and redemption, while keeping confidential the Creation Basket constituents of each series of Managed Portfolio Shares, including from the Authorized Participant. The books and records of the Confidential Account will be maintained by the AP Representative on behalf of the Authorized Participant.

[14] Rule 8.900–E(c)(3) provides that the term ''AP Representative'' means an unaffiliated broker-dealer, with which an Authorized Participant has signed an agreement to establish a Confidential Account for the benefit of such Authorized Participant, that will deliver or receive, on behalf of the Authorized Participant, all consideration to or from the Investment Company in a creation or redemption. An AP Representative will not be permitted to disclose the Creation Basket to any person, including the Authorized Participants.

[15] According to the Registration Statement, the Funds must comply with the federal securities laws in accepting Deposit Securities and satisfying redemptions with Redemption Securities, including that the Deposit Securities and Redemption Securities are sold in transactions that would be exempt from registration under the 1933 Act.

[16] To the extent that a Fund allows creations or redemptions to be conducted in cash, such transactions will be effected in the same manner for all APs transacting in cash.

marketplaces, to avoid revealing the composition of the Creation Basket.

Redemptions will occur primarily in-kind, although redemption payments may also be made partly or wholly in cash. The Participant Agreement signed by each AP will require establishment of a Confidential Account to receive distributions of securities in-kind upon redemption. Each AP will be required to open a Confidential Account with an AP Representative in order to facilitate orderly processing of redemptions.

Net Asset Value

The NAV will be calculated separately for the Shares of each Fund on each Business Day. Each Fund's NAV is determined as of the close of regular trading on the NYSE, normally 4:00 p.m., Eastern Time. The NAV of each Fund is computed by (i) taking the current market value of its total assets, (ii) subtracting any liabilities, and (iii) dividing that amount by the total number of shares owned by shareholders.

Each Fund generally values its portfolio investments at market prices. If market prices are unavailable or a Fund thinks that they are unreliable, or when the value of a security has been materially affected by events occurring after the relevant market closes, the Fund will price those securities at fair value as determined in good faith using methods approved by the Fund's Board.

More information about the valuation of each Fund's holdings can be found in the SAI.

Information showing the number of days that the market price of each Fund's Shares was greater than the Fund's NAV (*i.e.,* at a premium) or less than the Fund's NAV (*i.e.,* at a discount) for various time periods is available on the Funds' website at *www.advisorshares.com.*

Availability of Information

The Funds' website, *www.advisorshares.com,* 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 price, the bid/ask spreads at the time of calculation of such NAV (the ''Bid/Ask Price''),[17] and a calculation of the premium and discount of the market price or Bid/Ask Price against the NAV. The website and information will be publicly available at no charge.

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 SAI, its shareholder reports, its Form N–CSR, filed twice a year, and its Form N–CEN, filed annually. Each 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 onscreen or downloaded from the Commission's website at *www.sec.gov.*

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 Consolidated Tape Association (''CTA'') high-speed line. In addition, the Verified Intraday Indicative Value (''VIIV''), as defined in Rule 8.900–E(c)(2),[18] will be widely disseminated by the Reporting Authority [19] and/or one or more major market data vendors in one second intervals during the Exchange's Core Trading Session.

Dissemination of the VIIV

With respect to trading of the Shares, the ability of market participants to buy and sell Shares at prices near the VIIV is dependent upon their assessment that the VIIV is a reliable, indicative real-time value for a Fund's underlying holdings. Market participants are expected to accept the VIIV as a reliable, indicative real-time value because (1) the VIIV will be calculated and disseminated based on a Fund's actual portfolio holdings, (2) the securities in which a Fund plans to invest are generally highly liquid and actively traded and trade at the same time as the Fund and therefore generally have accurate real time pricing available, and (3) market participants will have a daily opportunity to evaluate whether the VIIV at or near the close of trading is indeed predictive of the actual NAV.

The VIIV will be widely disseminated by the Reporting Authority and/or by one or more major market data vendors in one second intervals during the Core Trading Session. The VIIV is based on the current market value of the securities in a Fund's portfolio that day. The methodology for calculating the VIIV will be available on the Funds' website. The VIIV is intended to provide investors and other market participants with a highly correlated per Share value of the underlying portfolio that can be compared to the current market price. Therefore, under normal circumstances the VIIV would be effectively a near real time approximation of each Fund's NAV, available free of charge from one or more market data vendors, which is computed only once a day.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of a Fund.[20] Trading in Shares of a Fund will be halted if the circuit breaker parameters in Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Shares will be subject to Rule 8.900–E(d)(2)(C), which sets forth circumstances under which Shares of a Fund will be halted.

Specifically, 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 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

[17] The Bid/Ask Price of a Fund's Shares is determined using 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.

[18] Rule 8.900–E(c)(2) provides that the term ''Verified Intraday Indicative Value'' is 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.

[19] Rule 8.900–E(c)(8) provides that the term ''Reporting Authority'' in respect of a particular series of Managed Portfolio Shares means 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.

[20] *See* Rule 7.12–E.

to the maintenance of a fair and orderly market are present.[21]

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 currently 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 net asset value, or the holdings are available, as required.

Trading Rules

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. Shares will trade on the Exchange in all trading sessions in accordance with Rule 7.34–E(a). As provided in Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00, for which the MPV for order entry is $0.0001.

The Shares will conform to the initial and continued listing criteria under Rule 8.900–E, as well as all terms in the Exemptive Application. 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.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of 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 Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products. As part of these surveillance procedures and consistent with Rule 8.900–E(b)(3) and 8.900–E(d)(2)(B), the Adviser will upon request make available to the Exchange and/or FINRA, on behalf of the Exchange, the daily portfolio holdings of a Fund. The issuer of the Shares of each Fund 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 Exchange 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 Exchange Rule 5.5–E(m).

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.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit (''ETP'') Holders in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares. Specifically, the Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares; (2) 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.

In addition, the Bulletin will reference that the Funds are subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. The Bulletin will also disclose that the NAV for the Shares will be calculated after 4:00 p.m., E.T. each trading day.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that this proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Funds would meet each of the rules relating to listing and trading of Managed Portfolio Shares. To the extent that a Fund is not in compliance with such rules, the Exchange would either prevent the Fund from listing and trading on the Exchange or commence delisting procedures under Rule 8.900–E(d)(2)(B). Specifically, the Exchange would consider the suspension of trading, and commence delisting proceedings under Rule 8.900–E(d)(2)(B), of a Fund under any of the following circumstances: (a) If, following the initial twelve-month period after commencement of trading on the Exchange, there are fewer than 50 beneficial holders of the Fund; (b) if the Exchange has halted trading in a Fund because the VIIV is interrupted pursuant to Rule 8.900–E(d)(2)(C)(ii) and such

[21] 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.

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

interruption persists past the trading day in which it occurred or is no longer available; (c) if the Exchange has halted trading in a Fund because the net asset value with respect to such Fund is not disseminated to all market participants at the same time, the holdings of such Fund are not made available on at least a quarterly basis as required under the 1940 Act, or such holdings are not made available to all market participants at the same time pursuant to Rule 8.900–E(d)(2)(C)(ii) and such issue persists past the trading day in which it occurred; (d) if the Exchange has halted trading in Shares of a Fund pursuant to Rule 8.900–E(d)(2)(C)(i) and such issue persists past the trading day in which it occurred; (e) if a Fund has failed to file any filings required by the Commission or if the Exchange is aware that a Fund is not in compliance with the conditions of any currently applicable exemptive order or no-action relief granted by the Commission or Commission staff with respect to the Fund; (f) if any of the continued listing requirements set forth in Rule 8.900–E are not continuously maintained; (g) if any of the statements of representations regarding (a) the description of the portfolio, (b) limitations on portfolio holdings, or (c) the applicability of Exchange listing rules as specified herein to permit the listing and trading of a Fund, are not continuously maintained; or (h) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

As discussed above, the Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer and has implemented and will maintain a ''fire wall'' with respect to such affiliate broker-dealer regarding access to information concerning the composition and/or changes to a Fund's portfolio and Creation Basket. In the event that (a) the Adviser or sub-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. 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.

In addition, Rule 8.900–E(b)(5) requires that any person or entity, including an AP Representative, custodian, Reporting Authority, distributor, or administrator, who has access to non-public information regarding the Investment Company's portfolio composition or changes thereto or the Creation Basket, must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the applicable Investment Company portfolio or changes thereto or the Creation Basket. Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity will erect and 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 Investment Company portfolio or Creation Basket. Any person or entity who has access to information regarding a Fund's portfolio composition 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 the portfolio or changes thereto or the Creation Basket.

The Exchange further believes that Rule 8.900–E is designed to prevent fraudulent and manipulative acts and practices related to the listing and trading of Shares of the Funds because it provides meaningful requirements about both the data that will be made publicly available about the Shares, as well as the information that will only be available to certain parties and the controls on such information. Specifically, the Exchange believes that the requirements related to information protection set forth in Rule 8.900–E(b)(5) will act as a safeguard against misuse and improper dissemination of information related to a Fund's portfolio composition, the Creation Basket, or changes thereto. The requirement that any person or entity implement procedures to prevent the use and dissemination of material non-public information regarding the portfolio or Creation Basket will act to prevent any individual or entity from sharing such information externally and the internal ''fire wall'' requirements applicable where an entity is a registered broker-dealer or affiliated with a broker-dealer will act to make sure that no entity will be able to misuse the data for their own purposes. Accordingly, the Exchange believes that this proposal is designed to prevent fraudulent and manipulative acts and practices.

The Exchange further believes that the proposal is designed to prevent fraudulent and manipulative acts and practices related to the listing and trading of Shares of the Funds and to promote just and equitable principles of trade and to protect investors and the public interest because the Exchange would halt trading under certain circumstances under which trading in the Shares of a Fund may be inadvisable. Specifically, trading in the Shares will be subject to Rule 8.900–E(d)(2)(C)(i), which provides that the Exchange may consider all relevant factors in exercising its discretion to halt trading in a Fund. Trading may be halted because of 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.[24] Additionally, trading in the Shares will be subject to Rule 8.900–E(d)(2)(C)(ii), which provides that the Exchange would halt trading where the Exchange becomes aware that: (a) The VIIV of a series of Managed Portfolio Shares is not being calculated or disseminated in one second intervals, as required; (b) the net asset value with respect to a series of Managed Portfolio Shares is not disseminated to all market participants at the same time; (c) 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 (d) such holdings are not made available to all market participants at the same time (except as otherwise permitted under the currently 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). The Exchange would halt trading in such Shares until such time as the VIIV, the NAV, or the holdings are available, as required.

With respect to the proposed listing and trading of Shares of the Funds, the Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be

[24] *See supra* note 21.

listed and traded on the Exchange pursuant to the initial and continued listing criteria in Rule 8.900–E.[25] Each Fund's holdings will conform to the permissible investments as set forth in the Exemptive Application.[26] As noted above, 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 the underlying exchange-traded instruments with other markets and other entities that are members of the ISG, and FINRA, on behalf of the Exchange, or the regulatory staff 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 and the underlying 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.

With respect to trading of Shares of the Funds, the ability of market participants to buy and sell Shares at prices near the VIIV is dependent upon their assessment that the VIIV is a reliable, indicative real-time value for a Fund's underlying holdings. Market participants are expected to accept the VIIV as a reliable, indicative real-time value because (1) the VIIV will be calculated and disseminated based on a Fund's actual portfolio holdings, (2) the securities in which the Funds plan to invest are generally highly liquid and actively traded and trade at the same time as the Funds and therefore generally have accurate real time pricing available, and (3) market participants will have a daily opportunity to evaluate whether the VIIV at or near the close of trading is indeed predictive of the actual NAV.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation that the NAV per Share of the Funds will be calculated daily and that the NAV will be made available to all market participants at the same time. Investors can also obtain a Fund's SAI, 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 will be available free upon request from the applicable Fund, 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.* In addition, a large amount of information will be publicly available regarding the Funds and the Shares, thereby promoting market transparency. Quotation and last sale information for the Shares will be available via the CTA high-speed line. Information regarding the VIIV will be widely disseminated in one second intervals throughout the Core Trading Session by the Reporting Authority and/or one or more major market data vendors. The website for the Funds will include a prospectus for the Funds that may be downloaded, and additional data relating to NAV and other applicable quantitative information, updated on a daily basis. Moreover, prior to the commencement of trading, the Exchange will inform its members in an Information Bulletin of the special characteristics and risks associated with trading the Shares.

In addition, as noted above, investors will have ready access to the VIIV, and quotation and last sale information for the Shares. The Shares will conform to the initial and continued listing criteria under Rule 8.900–E. 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, 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 investment objective.

The Exchange also believes that 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 in that it will facilitate the listing and trading of actively-managed exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the VIIV and quotation and last sale information for the Shares.

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 purposes of the Act. The Exchange believes the proposed rule change would permit the listing and trading of additional actively-managed exchange-traded products, thereby promoting competition among exchange-traded products 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

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

Within 45 days of the date of publication of this notice in the **Federal Register** or 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 the 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–NYSEArca–2020–94 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–2020–94. 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

[25] The Exchange represents that, for initial and/or continued listing, each Fund will be in compliance with Rule 10A–3 under the Act. *See* 17 CFR 240.10A–3.

[26] *See supra* note 9.

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–NYSEArca–2020–94, and should be submitted on or before November 30, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24786 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90327; File No. SR–NYSEAMER–2020–66]

Self-Regulatory Organizations; NYSE American, LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend the Exchange's Co-Location Services To Establish Procedures for the Allocation of Cabinets to Its Co-Located Users

November 3, 2020.

On September 2, 2020, NYSE American, LLC (''NYSE American'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish procedures as part of the Exchange's co-location rules to allocate cabinets to its co-located users in situations where the Exchange cannot satisfy the user demand for cabinets. The proposed rule change was published for comment in the **Federal Register** on September 21, 2020.[3] The Commission received no comments on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 5, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates December 20, 2020, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEAMER–2020–66).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24789 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89880 (September 15, 2020), 85 FR 59365 (SR–NYSEAMER–2020–66).

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–146, OMB Control No. 3235–0134]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F St NE, Washington, DC 20549–2736

Extension:
Rule 15c1–7

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 15c1–7 (17 CFR 240.15c1–7) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 15c1–7 states that any act of a broker-dealer designed to effect securities transactions with or for a customer account over which the broker-dealer (directly or through an agent or employee) has discretion will be considered a fraudulent, manipulative, or deceptive practice under the federal securities laws, unless a record is made of the transaction immediately by the broker-dealer. The record must include (a) the name of the customer, (b) the name, amount, and price of the security, and (c) the date and time when such transaction took place.

The Commission estimates that 362 respondents collect information related to approximately 400,000 transactions annually under Rule 15c1–7 and that each respondent would spend approximately 5 minutes on the collection of information for each transaction, for approximately 33,333 aggregate hours per year (approximately 92.1 hours per respondent).

Written comments are invited on: (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 estimates of the burden of the proposed collection of information; (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

respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 3, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24843 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–381, OMB Control No. 3235–0434]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 15g–2

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information provided for in Rule 15g–2 (17 CFR 240.15g–2) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). Rule 15g–2 (The ''Penny Stock Disclosure Rule'') requires broker-dealers to provide their customers with a risk disclosure document, as set forth in Schedule 15G, prior to their first non-exempt transaction in a ''penny stock.'' As amended, the rule requires broker-dealers to obtain written acknowledgement from the customer that he or she has received the required risk disclosure document. The amended rule also requires broker-dealers to maintain a copy of the customer's written acknowledgement for at least three years following the date on which the risk disclosure document was provided to the customer, the first two years in an accessible place. Rule 15g–2 also requires a broker-dealer, upon request of a customer, to furnish the customer with a copy of certain information set forth on the Commission's website.

The risk disclosure documents are for the benefit of the customers, to assure that they are aware of the risks of trading in ''penny stocks'' before they enter into a transaction. The risk disclosure documents are maintained by the broker-dealers and may be reviewed during the course of an examination by the Commission.

The Commission estimates that approximately 182 broker-dealers are engaged in penny stock transactions and that each of these firms processes an average of three new customers for penny stocks per week. The Commission further estimates that half of the broker-dealers send the penny stock disclosure documents by mail, and the other half send them through electronic means such as email. Because the Commission estimates the copying and mailing of the penny stock disclosure document takes two minutes, this means that there is an annual burden of 28,392 minutes, or 473 hours, for this third-party disclosure burden of mailing documents. Additionally, because the Commission estimates that sending the penny stock disclosure document electronically takes one minute, the annual burden is 14,196 minutes, or 237 hours, for this third-party disclosure burden of emailing documents.

Broker-dealers also incur a recordkeeping burden of approximately two minutes per response when filing the completed penny stock disclosure documents as required pursuant to the Rule 15g–2(c), which means that the respondents incur an aggregate recordkeeping burden of 56,784 minutes, or 946 hours.

Furthermore, Rule 15g–2(d) requires a broker-dealer, upon request of a customer, to furnish the customer with a copy of certain information set forth on the Commission's website, which takes a respondent no more than two minutes per customer. Because the Commission estimates that a quarter of customers who are required to receive the Rule 15g–2 disclosure document will request that their broker-dealer provide them with the additional microcap and penny stock information posted on the Commission's website, the Commission therefore estimates that each broker-dealer respondent processes approximately 39 requests for paper copies of this information per year or an aggregate total of 78 minutes per respondent, which amounts to an annual burden of 14,196 minutes, or 237 hours.

The Commission does not maintain the risk disclosure document. Instead, it must be retained by the broker-dealer for at least three years following the date on which the risk disclosure document was provided to the customer, the first two years in an accessible place. The collection of information required by the rule is mandatory. The risk disclosure document is otherwise governed by the internal policies of the broker-dealer regarding confidentiality, etc.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 4, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90322; File No. SR–FICC–2020–012]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Government Securities Division Rulebook To Clarify Which Funds-Only Settlement Payments and Underlying Marks Are Applicable to Certain Transactions, and Make Other Changes

November 3, 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 October 27, 2020, Fixed Income Clearing Corporation (''FICC'') 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. FICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(4) thereunder.[4] 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 consists of modifications to the FICC Government Securities Division (''GSD'') Rulebook (''Rules'')[5] in order to (i) clarify which funds-only settlement (''FOS'') payments and underlying ''marks''[6] are applicable to transactions in GSD's delivery-versus-payment (''DVP'') service (hereinafter ''DVP Transactions''),[7] clarify which payments and underlying marks are applicable to GCF Repo Transactions and CCIT Transactions, and add a payment that is currently debited from/credited to (as applicable) Members that is not currently referenced in the Rules, (ii) restructure Section 1 of Rule 13 to list only FOS payments rather than both payments and some underlying marks,[8] and (iii) make a correction and certain technical changes, as described in greater detail 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 purpose of the proposed rule change is to amend the Rules in order to: (i) Clarify which FOS payments and underlying marks are applicable to DVP Transactions, clarify which payments and underlying marks are applicable to GCF Repo Transactions and CCIT Transactions, and add a payment that is currently debited from/credited to (as applicable) Members that is not currently referenced in the Rules, (ii) restructure Section 1 of Rule 13 to list only FOS payments rather than both payments and some underlying marks, and (iii) make a correction and certain technical changes, as described in greater detail below.

(i) Background

FOS is FICC's twice daily process of generating a net credit or debit cash amount for each Member and settling those cash amounts between Members and FICC. FOS is a cash-pass-through process, meaning that those Members that are in a net debit position are obligated to submit payments that are then used to pay Members that are in a net credit position. FOS also includes certain payments that are not pass-through payments, such as Invoice Amounts and Miscellaneous Adjustment Amounts.

GSD processes FOS debit and credit payments via the Federal Reserve's National Settlement Service (''NSS'') twice daily at 10:00 a.m. and 3:15 p.m.

GSD FOS payments are set forth in Rule 13, Section 1. The FOS payments consist of (A) transaction adjustment payments for settlement purposes, (B) risk management-related amounts (such as various mark-to-market amounts), (C) security coupon and similar amounts, and (D) other amounts (such as the invoice amounts). A description of these payments is set forth below.

(A) Transaction Adjustment Payments for Settlement Purposes

The Transaction Adjustment Payment[9] applies to both DVP Transactions and GCF Repo Transactions that are settling the following Business Day (*i.e.,* the next Business Day after the Business Day on which the Transaction Adjustment Payment was calculated). As a central counterparty that performs a multilateral net process, FICC settles Net Settlement Positions at the System Value. The System Price is used to calculate the System Value. The Transaction Adjustment Payment adjusts the parties' original Contract Value of their pre-netted transaction to the Market Value[10] of the pre-netted transaction.

(B) Risk Management-Related Amounts

The risk management-related amounts apply throughout the life of a transaction to bring the transaction to market value (as applicable). These amounts therefore protect FICC and its Members from market risk in the event that there is a Member default and FICC must liquidate such transactions in the market; the closer the value of such transactions is to market, the smaller the amount of the loss that FICC would face in the liquidation of such transactions.

The risk management-related amounts currently set forth in Section 1 of Rule 13 are the following: (1) Forward Mark Adjustment Payment,[11] (2) GCF Interest Rate Mark,[12] (3) Interest Rate Mark,[13] (4) GCF Forward Mark,[14] and (5) Fail Mark Adjustment Payment.[15] In connection with the Forward Mark Adjustment Payment, there is a payment that reflects ''use of funds,'' (*i.e.,* Interest Adjustment Payment), as described below.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

[5] Capitalized terms not defined herein are defined in the Rules, *available at http://www.dtcc.com/legal/rules-and-procedures.*

[6] ''Marks'' refer to mark-to-market amounts that underlie or make up a FOS payment. For example, the Collateral Mark is an underlying component of the FOS payment known as the ''Forward Mark Adjustment Payment.''

[7] ''DVP Transactions'' refers to buy/sell transactions and Repo Transactions that are Direct Transactions and Brokered Transactions (other than GCF Repo Transactions and CCIT Transactions).

[8] Currently, Section 1 of Rule 13 references both payments and some of the underlying marks that make up payments. FICC wishes to provide clarity to this rule by limiting Section 1 to actual payments rather than underlying components that make up payments. This will be discussed in greater detail below.

[9] Rule 13, Section 1(a), *supra* note 5. The term ''Transaction Adjustment Payment'' means the absolute value of the dollar difference between the Contract Values and the Market Values of the trades that comprise a Net Settlement Position or GCF Net Settlement Position that is scheduled to settle on the current Business Day. Rule 1, *supra* note 5.

[10] The term ''Market Value'' means, on a particular Business Day, the amount in dollars equal to: (1) As regards a trade other than a Repo Transaction, the System Price established by FICC for the underlying Eligible Netting Securities, multiplied by the par value of such Securities, plus accrued coupon interest that has accrued with regard to such Securities calculated to their Scheduled Settlement Date, (2) as regards a Repo Transaction other than a GCF Repo Transaction, the System Price established by FICC for the underlying Eligible Netting Securities, multiplied by the par value of such Securities, plus accrued coupon interest that has accrued with regard to such Securities calculated to that Business Day, and (3) as regards a GCF Repo Transaction, the principal value of the Transaction. Rule 1, *supra* note 5.

Market Value applies to transactions, and System Value applies to Net Settlement Positions. Both values are derived using the System Price; for GCF Repo Transactions, Market Value means the principal value.

[11] Rule 13, Section 1(c), *supra* note 5.

[12] Rule 13, Section 1(d), *supra* note 5.

[13] Rule 13, Section 1(e), *supra* note 5.

[14] Rule 13, Section 1(f), *supra* note 5.

[15] Rule 13, Section 1(h), *supra* note 5.

(1) Forward Mark Adjustment Payment

Currently, the Forward Mark Adjustment Payment applies to both DVP Transactions and GCF Repo Transactions.[16] The Forward Mark Adjustment Payment equals the sum of 3 underlying marks (as applicable to a Member's Forward Net Settlement Position): (a) Collateral Mark, (b) Financing Mark, and (c) Interest Rate Mark. The Collateral Mark is a mark-to-market amount on Forward Trades (Contract Value versus Market Value). The Financing Mark is a mark-to-market amount on the repo rate of a Repo Transaction that has a start date prior to current Business Day. The Interest Rate Mark is a mark-to-market amount on the repo rate for a Forward-Starting Repo Transaction.

In addition, in connection with the Forward Mark Adjustment Payment, there is a payment called the Interest Adjustment Payment[17] that reflects ''use of funds.'' This means that FICC will charge overnight interest to the Member that received the Forward Mark Adjustment Payment as a credit and this interest amount will be paid to the Member that was charged the Forward Mark Adjustment Payment as a debit. As FICC is passing through a cash payment for risk management purposes, the Member who receives the cash has use of those funds, and the Member who was debited does not have use of those funds. Because the funds belong to the Member who was debited, such Member is entitled to, and receives, the interest income on the amount that was debited.

(2) GCF Interest Rate Mark

The GCF Interest Rate Mark[18] is the mark-to-market amount on the repo rate of a GCF Repo Transaction that has started (typically referred to as an ''in-flight'' transaction).

(3) Interest Rate Mark

As discussed above, the Interest Rate Mark[19] is an underlying component of the Forward Mark Adjustment Payment. In addition to applying to DVP Transactions as stated above, the Interest Rate Mark also applies to GCF Repo Transactions, and is a mark-to-market amount on the repo rate of a forward-starting GCF Repo Transaction.

Similar to the Interest Adjustment Payment, the Interest Rate Mark Adjustment Payment[20] is the interest paid or collected for ''use of funds'' in connection with the sum of a Member's GCF Interest Rate Mark and Interest Rate Mark.

(4) GCF Forward Mark

The GCF Forward Mark[21] is currently stated to be the sum of the Accrued Repo Interest-to-Date and the GCF Interest Rate Mark.

(5) Fail Mark Adjustment Payment

The Fail Mark Adjustment Payment[22] is a mark-to-market amount for obligations that were scheduled to settle and have not yet settled.

(C) Security Coupon and Similar Amounts

FOS includes certain coupon and similar payments as follows: (1) Delivery Differential Adjustment Payment,[23] (2) Coupon Adjustment Payment,[24] and (3) Clearance Difference Amount.[25]

The Delivery Differential Adjustment Payment[26] is the amount of the difference between the Federal Reserve's auction award price and FICC's System Price.

The Coupon Adjustment Payment[27] is the amount that reflects coupon interest from the issuer of the security that is passed to a Member.

The Clearance Difference Amount[28] is the amount of any differences that may occur between the amounts that are reflected in FICC's records versus the Clearing Agent Bank.

(D) Other Amounts

The other amounts that are part of GSD FOS are as follows: (1) Invoice Amount[29] and (2) Miscellaneous Adjustment Amount.[30]

[16] The term ''Forward Mark Adjustment Payment'' means, on a particular Business Day, as regards a Member's Forward Net Settlement Position, the sum of the Collateral Mark applicable to such Position, the Financing Mark applicable to such Position, and the Interest Rate Mark applicable to such Position. Notwithstanding the above, as regards an outstanding Repo Transaction where a request for substitution has been made but New Securities Collateral has not been received by FICC, the term ''Forward Mark Adjustment Payment'' means ''Forward Unallocated Sub Mark.'' Rule 1, *supra* note 5.

[17] Rule 13, Section 1(g), *supra* note 5.

[18] The term ''GCF Interest Rate Mark'' means, on a particular Business Day as regards any GCF Repo Transaction that is not scheduled to settle on that day, the product of the principal value of the GCF Repo Transaction on the Scheduled Settlement Date for its End Leg multiplied by a factor equal to the absolute difference between the Repo Rate established by FICC for such Repo Transaction and its Contract Repo Rate, and then multiplied by a fraction, the numerator of which is the number of calendar days from the current day until the Scheduled Settlement Date for the End Leg of the Repo Transaction and the denominator of which is 360. If the Repo Transaction's Contract Repo Rate is greater than its System Repo Rate, then the GCF Interest Rate Mark shall be a positive value for the Reverse Repo Party, and a negative value for the Repo Party. If the Repo Transaction's Contract Repo Rate is less than its System Repo Rate, then the GCF Interest Rate Mark shall be a positive value for the Repo Party, and a negative value for the Reverse Repo Party. The term ''GCF Interest Rate Mark'' means, as regards a GCF Net Settlement Position, the sum of all the GCF Interest Rate Mark Payments on each of the GCF Repo Transactions that compose such position. Rule 1, *supra* note 5.

[19] The term ''Interest Rate Mark'' means, on a particular Business Day as regards a Forward-Starting Repo Transaction during its Forward-Starting Period, the product of the principal value of the Repo Transaction on the Scheduled Settlement Date for its Start Leg multiplied by a factor equal to the absolute difference between the System Repo Rate established by FICC for such Repo Transaction and its Contract Repo Rate, and then multiplied by a fraction, the numerator of which is the number of calendar days from the Scheduled Settlement Date for the Start Leg of the Repo Transaction until the Scheduled Settlement Date for the End Leg of the Repo Transaction and the denominator of which is 360. If the Repo Transaction's Contract Repo Rate is greater than its System Repo Rate, then the Interest Rate Mark shall be a positive value for the Reverse Repo Party, and a negative value for the Repo Party. If the Repo Transaction's Contract Repo Rate is less than its System Repo Rate, then the Interest Rate Mark shall be a positive value for the Repo Party, and a negative value for the Reverse Repo Party. The Interest Rate Mark for any Repo Transaction other than a Forward-Starting Repo Transaction during its Forward-Starting Period, and for any trade other than a Repo Transaction, shall be zero. The term ''Interest Rate Mark'' means, as regards a Forward Net Settlement Position, the sum of all the Interest Rate Marks on each of the Forward Trades that compose such position. Rule 1, *supra* note 5.

[20] Rule 13, Section 1(f), *supra* note 5. The term ''Interest Rate Mark Adjustment Payment'' means, as regards the sum of a Netting Member's GCF Interest Rate Mark and Interest Rate Mark, the product of that sum multiplied by the applicable Overnight Investment Rate and then multiplied by a fraction, the numerator of which is the number of calendar days between the previous Business Day and the current Business Day and the denominator of which is 360. Rule 1, *supra* note 5.

[21] The term ''GCF Forward Mark'' means, on a particular Business Day as regards any GCF Repo Transaction that is not scheduled to settle on that day, the sum of the Accrued Repo Interest-to-Date and the GCF Interest Rate Mark on such GCF Repo Transaction. Rule 1, *supra* note 5.

[22] The term ''Fail Mark Adjustment Payment'' means the absolute value of the dollar difference between the Settlement Value of a Fail Deliver Obligation or a Fail Receive Obligation that constitutes all or part of a Fail Net Settlement Position on the current Business Day and the Settlement Value of such Fail Deliver Obligation or Fail Receive Obligation on the immediately previous Business Day. Rule 1, *supra* note 5.

[23] Rule 13, Section 1(b), *supra* note 5.

[24] Rule 13, Section 1(i) and Section 1(j), *supra* note 5.

[25] Rule 13, Section 1(k), *supra* note 5.

[26] The term ''Delivery Differential Adjustment Payment'' means the absolute value of the dollar difference between the System Value and the Settlement Value of a Netting Member's Deliver Obligation or a Receive Obligation. Rule 1, *supra* note 5.

[27] The term ''Coupon Adjustment Payment'' means the coupon payments due and owing on each Eligible Netting Security that comprises either a Coupon-Eligible End Leg or a Fail Net Settlement Position. Rule 1, *supra* note 5.

[28] The term ''Clearance Difference Amount'' means the absolute value of the dollar difference between the Settlement Value of a Deliver Obligation or a Receive Obligation and the actual value at which such Deliver Obligation or Receive Obligation was settled, by the delivery or receipt of Eligible Netting Securities. Rule 1, *supra* note 5.

[29] Rule 13, Section 1(l), *supra* note 5.

[30] Rule 13, Section 1(m), *supra* note 5.

The Invoice Amount [31] is a Member's billing amount.

The Miscellaneous Adjustment Amount [32] is a catch-all amount, in case it is needed.

(ii) Proposed Rule Changes

The purpose of the proposed rule change is to amend the Rules in order to: (A) Clarify which FOS payments and underlying marks are applicable to DVP Transactions, clarify which payments and underlying marks are applicable to GCF Repo Transactions and CCIT Transactions, and add a payment that is currently debited from/credited to (as applicable) Members that is not currently referenced in the Rules, (B) restructure Section 1 of Rule 13 to list only FOS payments rather than both payments and some underlying marks, and (C) make a correction and certain technical changes, as described in greater detail below.

(A) Clarify Which FOS Payments and Underlying Marks are Applicable to DVP Transactions, Clarify Which Payments and Underlying Marks are Applicable to GCF Repo Transactions and CCIT Transactions, and add a Payment That is Currently Debited From/Credited to (as applicable) Members That is not Currently Referenced in the Rules

At this time, Section 1 of Rule 13 includes references to payments and certain underlying marks. Some of these payments and marks as currently defined apply to both DVP Transactions and GCF Repo Transactions. In order to provide more clarity, FICC proposes to amend the Rules to clarify which FOS payments are applicable to DVP Transactions and which FOS payments are applicable to GCF Repo Transactions. This proposal would not change the way FICC operates or the payments/marks applicable to GCF Repo Transactions, but instead would take out defined terms from more general definitions in order to be more standalone. Specifically, FICC would clarify Rule 1 by amending certain existing defined terms, deleting certain existing defined terms and adding new defined terms, as described further below.

Furthermore, FICC would amend Rule 13 to specifically list the FOS payments that are applicable to DVP Transactions and the FOS payments that are applicable to GCF Repo Transactions, as further described below.

DVP Transactions

As described above, certain FOS payments and underlying marks would be revised to clarify that they only apply to DVP Transactions. The Forward Mark Adjustment Payment is a risk management-related amount that equals the sum of 3 underlying marks (as applicable to a Member's Forward Net Settlement Position): (a) Collateral Mark, (b) Financing Mark, and (c) Interest Rate Mark. FICC proposes to clarify that the Forward Mark Adjustment Payment and its underlying marks, the Collateral Mark, Financing Mark, and Interest Rate Mark, would apply only to DVP Transactions. As such, FICC proposes to revise the definitions of Collateral Mark, Financing Mark, Interest Rate Mark, and Forward Mark Adjustment Payment in Rule 1 to clarify that these terms do not apply to GCF Repo Transactions and CCIT Transactions.

Furthermore, FICC is proposing to delete the defined term Interest Rate Mark Adjustment Payment (and its credit, debit and net equivalents, the Debit Interest Rate Mark Adjustment Payment, Credit Interest Rate Mark Adjustment Payment, and Net Interest Rate Mark Adjustment Payment) in Rule 1, because FICC believes it would enhance clarity to amend the Rules to have separate terms to describe what this FOS payment covers for GCF Repo Transactions and DVP Transactions. This FOS payment covers ''use of funds'' as described above. For DVP Transactions, FICC would retain Interest Adjustment Payment, as currently defined, for ''use of funds'' purposes. FICC would amend Rule 1 to add the specific term GCF Interest Adjustment Payment, which would be applicable to GCF Repo Transactions and with respect to CCIT Transactions, only as stipulated in Rule 3B.

In addition, FICC proposes to amend the definitions of Credit Transaction Adjustment Payment, Debit Transaction Adjustment Payment and Transaction Adjustment Payment in Rule 1 to state that these terms apply to DVP Transactions. Specifically, FICC proposes to delete the reference to GCF Net Settlement Position in the definition of Transaction Adjustment Payment, and the descriptions related to GCF Net Settlement Position in the definitions of Credit Transaction Adjustment Payment and Debit Transaction Adjustment Payment in Rule 1. The definition of Transaction Adjustment Payment would also be amended to add that it would not apply to GCF Repo Transactions and CCIT Transactions. FICC would delete the reference to GCF Net Settlement Position in Section 1(a) of Rule 13 because this Section 1(a) describes Transaction Adjustment Payments (which would be revised to only describe payments for settlement purposes for DVP Transactions). FICC would also add the defined term GCF Transaction Adjustment Payment to Rule 1, as described below.

Coupon Adjustment Payment, Clearance Difference Amount and Delivery Differential Adjustment Payment currently apply only to DVP Transactions. As such, FICC proposes to revise the definitions of Coupon Adjustment Payment, Coupon-Eligible End Leg, Fail Mark Adjustment Payment, and Clearance Difference Amount (and its credit and debit equivalents, Credit Clearance Difference Amount and Debit Clearance Difference Amount), and Delivery Differential Adjustment Payment to clarify that these terms do not apply to GCF Repo Transactions and CCIT Transactions.[33]

FICC also proposes to add a new defined term, Redemption Adjustment Payment (and its credit, debit and net equivalents, Credit Redemption Adjustment Payment, Debit Redemption Adjustment Payment, and Net Redemption Adjustment Payment) to Rule 1 to reflect an amount that is currently being debited from/credited to Members today. For a Net Settlement Position, the Redemption Adjustment Payment means the difference between the Redemption Value (as defined below and in the proposed rule change) and the Settlement Value due and owing on each Eligible Netting Security that comprises such position. For the End Leg of a Repo Transaction, the Redemption Adjustment Payment means the difference between the Maturity Value and the Contract Value due and owing on each Eligible Netting Security that comprises such Transaction. If the Redemption Adjustment Payment is a positive value, it would be a Credit Redemption Adjustment Payment. If the Redemption Adjustment Payment is a negative value, it would be a Debit Redemption Adjustment Payment. Net Redemption Adjustment Payment would mean the absolute dollar value difference on a

[31] The term ''Invoice Amount'' means all fee amounts due and owing from a Netting Member or CCIT Member, as applicable, to FICC on a particular Business Day. Rule 1, *supra* note 5.

[32] The term ''Miscellaneous Adjustment Amount'' means the net total of all miscellaneous funds-only amounts that, on a particular Business Day, are required to be paid by a Netting Member or CCIT Member, as applicable, to FICC and/or are entitled to be collected by a Member (including a CCIT Member, as applicable) from FICC. Rule 1, *supra* note 5.

[33] As described above, the term ''Coupon Adjustment Payment'' means the coupon payments due and owing on each Eligible Netting Security that comprises either a Coupon-Eligible End Leg or a Fail Net Settlement Position. Rule 1, *supra* note 5.

particular Business Day for a Netting Member between the total of all Credit Redemption Adjustment Payments and the total of all Debit Redemption Adjustment Payments.[34]

FICC also proposes to add the defined term Redemption Value to Rule 1, which would mean, as regards a Net Settlement Position or a Deliver Obligation, the principal amount paid to the holder of such position or obligation in redeeming Eligible Netting Securities at the maturity for such securities.

GCF Repo Transactions and CCIT Transactions

Furthermore, FICC proposes to add certain defined terms associated with FOS that would be applicable only to GCF Repo Transactions and CCIT Transactions.

Specifically, FICC proposes to add GCF Forward Mark Adjustment Payment (and its credit, debit and net equivalents, Credit GCF Forward Mark Adjustment Payment, Debit GCF Forward Mark Adjustment Payment, and Net GCF Forward Mark Adjustment Payment) to Rule 1. These proposed terms would only be applicable to GCF Repo Transactions.

FICC also proposes to add GCF Transaction Adjustment Payment (and its credit, debit, and net equivalents, Credit GCF Transaction Adjustment Payment, Debit GCF Transaction Adjustment Payment, and Net GCF Transaction Adjustment Payment) to Rule 1. These proposed terms would be applicable to both GCF Repo Transactions and CCIT Transactions.

In addition, FICC proposes to add the following terms to Rule 1, which would be applicable to GCF Repo Transactions and with respect to CCIT Transactions, only as stipulated in Rule 3B: (1) GCF Forward Starting Interest Rate Mark, and (2) GCF Interest Adjustment Payment (and its credit, debit and net equivalents, Credit GCF Interest Adjustment Payment, Debit GCF Interest Adjustment Payment, and Net GCF Interest Adjustment Payment).

GCF Forward Mark and GCF Forward Mark Adjustment Payment

While GCF Forward Mark is referenced in Rule 13, Section 1(f) and is defined to be the sum of Accrued Repo Interest-to-Date and GCF Interest Rate Mark, FICC believes that Section 1 of Rule 13 should be clarified to reference an actual payment (the proposed ''GCF Forward Mark Adjustment Payment'') that represents the payment of this mark (which is discussed below). FICC also proposes to revise the definition of GCF Forward Mark in Rule 1 to include the new defined term GCF Forward Starting Interest Rate Mark. FICC is currently collecting the amount represented by the proposed GCF Forward Starting Interest Rate Mark, and the addition of this reference to the definition of GCF Forward Mark is not a substantive change.

The GCF Forward Mark Adjustment Payment would apply only to GCF Repo Transactions and would mean, on a particular Business Day, as regards a Member's Forward Net Settlement Position, the payment as it relates to the Member's GCF Forward Mark. If the GCF Forward Mark Adjustment Payment is a positive value, it would be a Credit GCF Forward Mark Adjustment Payment. If the GCF Forward Mark Adjustment Payment is a negative value, then it would be a Debit GCF Forward Mark Adjustment Payment. Net GCF Forward Mark Adjustment Payment would mean the absolute value of the dollar difference on a particular Business Day for a Netting Member between the total of all Credit GCF Forward Mark Adjustment Payments and the total of all of the Debit GCF Forward Mark Adjustment Payments.[35]

GCF Forward Starting Interest Rate Mark

GCF Forward Starting Interest Rate Mark would be applicable only to GCF Repo Transactions and with respect to CCIT Transactions, only as stipulated in Rule 3B, and would be the equivalent term to Interest Rate Mark for DVP Transactions. Like Interest Rate Mark for DVP Transactions, this would be a mark (or underlying component) of a FOS payment. Specifically, this mark would be part of the GCF Forward Mark, which is a FOS payment that is applicable to Forward-Starting Repo Transactions that are GCF Repo Transactions.

GCF Interest Adjustment Payment

FICC also proposes to add the defined term GCF Interest Adjustment Payment (and its credit, debit and net equivalents, the Credit GCF Interest Adjustment Payment, Debit GCF Interest Adjustment Payment, and Net GCF Interest Adjustment Payment) to Rule 1. This term would be applicable to GCF Repo Transactions and with respect to CCIT Transactions, as stipulated in Rule 3B, and would be the equivalent term to Interest Adjustment Payment for DVP Transactions.

GCF Transaction Adjustment Payment

The current definition of Transaction Adjustment Payment covers both FOS payments applicable to DVP Transactions and those that are applicable to GCF Repo Transactions. In order to enhance clarity, as described above, FICC would distinguish between the FOS payments that are applicable to DVP Transactions and those that are applicable to GCF Repo Transactions. Specifically, as described above, FICC would add the defined term GCF Transaction Adjustment Payment (and its credit, debit and net equivalents, the Credit GCF Transaction Adjustment Payment, Debit GCF Transaction Adjustment Payment, and Net GCF Transaction Adjustment Payment) to Rule 1.

GCF Transaction Adjustment Payment would mean, as regards a Netting Member, the total repo interest on the Netting Member's GCF Repo Transactions and CCIT Transactions, as applicable, for which the Scheduled Settlement Date for the End Leg of such transactions is the next Business Day.

If the GCF Transaction Adjustment Payment is a positive value, it would be a Credit GCF Transaction Adjustment Payment. If the GCF Transaction Adjustment Payment is a negative value, it would be a Debit GCF Transaction Adjustment Payment. Net GCF Transaction Adjustment Payment would mean, on a particular Business Day, the absolute value of the dollar difference between the total of all Credit GCF Transaction Adjustment Payments and the total of all Debit GCF Transaction Adjustment Payments for a Netting Member.[36]

[34] If the total of all of the Credit Redemption Adjustment Payments is greater than all of the Debit Redemption Adjustment Payments, then the Net Redemption Adjustment Payment would be a positive dollar amount owing from FICC to the Member. If the total of all the Credit Redemption Adjustment Payments is less than the total of all of the Debit Redemption Adjustment Payments, then the Net Redemption Adjustment Payment would be a negative dollar amount owing from the Member to FICC.

[35] If the total of all of the Credit GCF Forward Mark Adjustment Payments is greater than the total of all of the Debit GCF Forward Mark Adjustment Payments, then the Net GCF Forward Mark Adjustment Payment would be a positive dollar amount owing from FICC to the Member. If the total of all of the Credit GCF Forward Mark Adjustment Payments is less than the total of all of the Debit GCF Forward Mark Adjustment Payments, then the Net GCF Forward Mark Adjustment Payment would be a negative dollar amount owing from the Member to FICC.

[36] If the total of all of the Credit GCF Transaction Adjustment Payments is greater than the total of all of the Debit GCF Transaction Adjustment Payments, then the Net GCF Transaction Adjustment Payment would be a positive dollar amount owing from FICC to the Member. If the total of all of the Credit GCF Transaction Adjustment Payments is less than the total of all of the Debit GCF Transaction Adjustment Payments, then the Net GCF Transaction Adjustment Payments would be a negative dollar amount owing from the Member to FICC.

FICC would also amend the definition of Transaction Adjustment Payment so that it would be applicable only to DVP Transactions, as described above.

Forward-Starting Period and Forward-Starting Repo Transaction

FICC also proposes to clarify that the definitions of Forward-Starting Period and Forward-Starting Repo Transaction in Rule 1 include CCIT Transactions. As such, FICC would amend the definitions of Forward-Starting Period and Forward-Starting Repo Transaction in Rule 1 to reference CCIT Transactions.

Rule 3B

In addition, FICC proposes to revise Section 13(b) of Rule 3B, which describes the FOS payments that apply to Netting Members with respect to their CCIT Transactions. In Section 13(b)(i) of Rule 3B, Transaction Adjustment Payment would be revised to the new proposed term GCF Transaction Adjustment Payment. As described above, with respect to CCIT Transactions and GCF Repo Transactions, GCF Transaction Adjustment Payment would be the equivalent term to Transaction Adjustment Payment for DVP Transactions. GCF Transaction Adjustment Payment, like Transaction Adjustment Payment, would describe payments for settlement purposes.

Similarly, the references in Section 13(b)(iii) of Rule 3B to Interest Rate Mark would be revised to GCF Forward Starting Interest Rate Mark. GCF Forward Starting Interest Rate Mark would apply only to GCF Repo Transactions and with respect to CCIT Transactions, as stipulated in Rule 3B, and would be equivalent to the current defined term Interest Rate Mark (which, as described above, would be amended to clarify that it only applies to DVP Transactions). Like Interest Rate Mark for DVP Transactions, GCF Forward Starting Interest Rate Mark would be an underlying mark of a FOS payment, the proposed GCF Forward Mark Adjustment Payment. GCF Forward Mark Adjustment Payment is a FOS payment for risk management-related amounts and is applicable to Forward-Starting Repo Transactions that are a GCF Repo Transactions. As described above, the definition of GCF Forward Mark would be revised to include GCF Forward Starting Interest Rate Mark, so it would state that, on a particular Business Day as regards any GCF Repo Transaction that is not scheduled to settle on that day, the sum of the Accrued Repo Interest-to-Date, the GCF Forward Starting Interest Rate Mark and the GCF Interest Rate Mark on such GCF Repo Transaction.

Furthermore, in Section 13(b)(iv) of Rule 3B, FICC would revise the reference from Interest Rate Mark Adjustment Payment to GCF Interest Adjustment Payment and would add that the GCF Interest Adjustment Payment is as it relates to (ii) and (iii) of Section 13(b) of Rule 3B. Current Section 13(b)(ii) of Rule 3B specifies that Netting Members are obligated to pay debits but are not entitled to collect credits for GCF Interest Rate Mark with respect to their CCIT Transactions. As described above, Section 13(b)(iii) of Rule 3B would be revised to reference the GCF Forward Starting Interest Rate Mark rather than the Interest Rate Mark. Netting Members would be obligated to pay debits but would not be entitled to collect credits for the GCF Forward Starting Interest Rate Mark with respect to their CCIT Transactions. As described above, GCF Interest Adjustment Payment would be added as a new defined term and would be equivalent to the current defined term, Interest Adjustment Payment (which would apply only to DVP Transactions). As described above, FICC is proposing to delete the term Interest Rate Mark Adjustment Payment because this payment would be covered by the new defined term GCF Interest Adjustment Payment (which would apply to GCF Repo Transactions and with respect to CCIT Transactions, only as stipulated in Rule 3B) and the current defined term, Interest Adjustment Payment (which would apply only to DVP Transactions).

(B) Restructure Section 1 of Rule 13 To List Only FOS Payments Rather Than Both Payments and Some Underlying Marks

FICC believes it would enhance clarity and consistency in Rule 13 to only list the FOS payments in Section 1 of Rule 13 (and not the underlying marks). Currently, Section 1 of Rule 13 lists both FOS payments and some underlying marks. Specifically, Sections 1(d), (e), and (f) of Rule 13 lists the GCF Interest Rate Mark, the Interest Rate Mark, Debit Interest Rate Marks, Debit GCF Forward Marks and Credit Interest Rate Marks and Credit GCF Forward Marks, which are underlying marks of FOS payments. As such, FICC proposes to delete current Sections 1(d), (e), and (f) of Rule 13.

FICC also proposes to amend Rule 13 by adding the new proposed FOS payment, Redemption Adjustment Payment, as proposed Section 1(h).

FICC also proposes to amend Rule 13 by adding the new proposed FOS payments that are applicable to GCF Repo Transactions (GCF Transaction Adjustment Payment, GCF Forward Mark Adjustment Payment, and GCF Interest Adjustment Payment) as proposed Sections 1(j), (k), and (l).

(C) *A Correction and Certain Technical Changes*

FICC is proposing to make corrections to the definition of Forward Trade to reflect FICC's practice. FICC is correcting that a Repo Transaction may be a Forward Trade (the current definition excludes Repo Transactions in error). In addition, FICC is also adding a sentence to make clear that if the Forward Trade is a Repo Transaction, the Start Leg and the End Leg would be considered separate trades. FICC is making a correction to provide that a Forward Trade is a trade whose Scheduled Settlement Date is one or more Business Days after the date it is submitted to FICC (not two or more Business Days as is currently stated in the definition). These corrections are necessary to ensure that the definition of Forward Trade reflects current practice. Specifically, the definition of Forward Trade must be consistent with the definition of Forward Net Settlement Position, which is made up of a Member's Forward Trades. The definition of Forward Net Settlement Position provides that the Scheduled Settlement Date of a Forward Trade is one or more Business Days in the future, it includes Repo Transactions, and provides the Start and End Legs shall constitute separate positions. These are the items that FICC is proposing to correct in the definition of Forward Trade. These corrections to the definition of Forward Trade are relevant to the FOS process because under FICC's current process, a Forward Mark Adjustment Payment is applied to Forward Trades that are T+1 trades.

FICC is also proposing to make certain technical changes, such as conforming grammatical changes, capitalizing defined terms, renumbering sections, and reordering a list. For example, in Rule 1, FICC proposes to make a conforming grammatical change to add ''and a'' in the definition of Forward-Starting Period because a reference to CCIT Transaction would be added. As another example, because FICC is adding a new defined term, Redemption Value, in Rule 1, FICC proposes to capitalize the references to redemption value in the definition of Maturity Value and System Value.

In addition, certain paragraphs would be deleted or added in Rule 13, so FICC proposes to make conforming technical changes to renumber these paragraphs accordingly.

FICC would also make conforming changes to Section 2 of Rule 13, which currently states that the Funds-Only Settlement Amount of each Netting Member is determined by calculating the net total, for a particular Business Day, of the payments and underlying marks set forth in that section. FICC proposes to delete the following terms: The Net Interest Rate Mark Adjustment Payment, the GCF Interest Rate Mark, and the Interest Rate Mark. FICC would add the new proposed terms, Net GCF Transaction Adjustment Payment, Net GCF Forward Mark Adjustment Payment, Net GCF Interest Adjustment Payment, and Net Redemption Adjustment Payment.

In order to enhance clarity and consistency, FICC proposes to reorder the list of payments that make up the Funds-Only Settlement Amount in Section 2 of Rule 13. Currently, the Net Coupon Adjustment Payment and the Net Clearance Difference Amount are listed as items (i) and (j) in the second paragraph of Section 2 of Rule 13. FICC proposes to move the Net Coupon Adjustment Payment to new item (f) and the Net Clearance Difference Amount to new item (g) to be consistent with the order in which these payments appear in Section 1 of Rule 13. FICC would also make a conforming change to renumber the subsections in Section 2 of Rule 13 accordingly.

In addition, FICC is proposing to delete the reference to the term ''Clearing Fund Funds-Only Settlement Amount'' from the definition of Opening Balance in Rule 1, because this is an outdated Clearing Fund component that should have been deleted when GSD moved to a VaR-based Clearing Fund methodology. FICC is also proposing to clarify the definition by deleting ''on a given Business Day'' and ''of the previous Business Day'' from the definition of Opening Balance and adding ''immediately prior'' before processing cycle because, as described above, FOS occurs twice daily. As such, the Opening Balance of the intraday FOS would be the amount reported to the Member during the morning FOS cycle.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.[37]

The proposed changes to (i) clarify which FOS payments and underlying marks are applicable to DVP Transactions, clarify which payments and underlying marks are applicable to GCF Repo Transactions and CCIT Transactions, and add a payment that is currently debited from/credited to (as applicable) Members that is not currently referenced in the Rules, (ii) restructure Section 1 of Rule 13 to list only FOS payments rather than both payments and some underlying marks, and (iii) make a correction and certain technical changes to the Rules would help to ensure that the Rules are accurate and clear to participants. When participants better understand their rights and obligations regarding the Rules, such participants are more likely to act in accordance with the Rules, which FICC believes would promote the prompt and accurate clearance and settlement of securities transactions. As such, FICC believes that the proposed changes are consistent with Section 17A(b)(3)(F) of the Act.[38]

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe the proposed rule changes to (i) clarify which FOS payments and underlying marks are applicable to DVP Transactions, clarify which payments and underlying marks are applicable to GCF Repo Transactions and CCIT Transactions, and add a payment that is currently debited from/credited to (as applicable) Members that is not currently referenced in the Rules, (ii) restructure Section 1 of Rule 13 to list only FOS payments rather than both payments and some underlying marks, and (iii) make a correction and certain technical changes would impact competition. The proposed rule changes would help to ensure that the Rules remain clear and accurate. In addition, the changes would facilitate participants' understanding of the Rules and their obligations thereunder. These changes would not affect FICC's operations or the rights and obligations of the membership. As such, FICC believes the proposed rule changes would not have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)[39] of the Act and paragraph (f)[40] of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–FICC–2020–012 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–FICC–2020–012. 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

[37] 15 U.S.C. 78q–1(b)(3)(F).

[38] *Id.*

[39] 15 U.S.C 78s(b)(3)(A).

[40] 17 CFR 240.19b–4(f).

filing also will be available for inspection and copying at the principal office of FICC 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–FICC–2020–012 and should be submitted on or before November 30, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[41]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24785 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

[41] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90329; File No. SR–NYSENAT–2020–28]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend the Exchange's Co-Location Services To Establish Procedures for the Allocation of Cabinets to Its Co-Located Users

November 3, 2020.

On September 2, 2020, NYSE National, Inc., (''NYSE National'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish procedures as part of the Exchange's co-location rules to allocate cabinets to its co-located users in situations where the Exchange cannot satisfy the user demand for cabinets. The proposed rule change was published for comment in the **Federal Register** on September 22, 2020.[3] The Commission received no comments on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 6, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates December 21, 2020, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSENAT–2020–28).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24791 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release Nos. 89884 (September 16, 2020), 85 FR 59576 (SR–NYSENAT–2020–28).

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–184, OMB Control No. 3235–0236]

Proposed Collection; Comment Request

Extension:

Form N–54C

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Certain investment companies can elect to be regulated as business development companies, as defined in section 2(a)(48) of the Investment Company Act of 1940 (''Investment Company Act''), under sections 55 through 65 of the Investment Company Act. Under section 54(a) of the Investment Company Act,[1] any company defined in section 2(a)(48)(A) and (B) of the Investment Company Act may, if it meets certain enumerated eligibility requirements, elect to be subject to the provisions of Sections 55 through 65 of the Investment Company Act by filing with the Commission a notification of election. Under section 54(c) of the Investment Company Act,[2] any business development company may voluntarily withdraw its election under section 54(a) of the Investment Company Act by filing a notice of withdrawal of election with the Commission. The Commission has adopted Form N–54C as the form for the notification of withdrawal of election to be subject to Sections 55 through 65 of the Investment Company Act. The purpose of Form N–54C is to notify the Commission that the business development company withdraws its election to be subject to Sections 55 through 65 of the Investment Company Act.

The Commission estimates that on average approximately eight business development companies file notifications on Form N–54C each year. Each of those business development companies need only make a single filing of Form N–54C. The Commission further estimates that this information collection imposes a burden of one hour, resulting in a total annual burden of eight hours. Based on the estimated wage rate, the total cost to the business development company industry of the hour burden for complying with Form N–54C would be approximately $2,944.[3] The Commission also estimates that cost burden for outside professionals associated with the filing of Form N–54C increased to $560 because the Commission believes that filers use third-party vendors to comply with this requirement.

The collection of information under Form N–54C is mandatory. The information provided by the form is not kept confidential. An agency may not

[1] 15 U.S.C. 80a–53(a).

[2] 15 U.S.C. 80a–53(c).

[3] The industry burden is calculated by multiplying the total annual hour burden to prepare Form N–54C (eight) by the estimated hourly wage rate of $368 for a compliance attorney or other similarly situated business development company employee. The estimated wage figure is based on published rates for compliance attorneys from the Securities Industry and Financial Markets Association's Report on Management & Professional Earnings in the Securities Industry 2013, modified by Commission staff to account for an 1,800 hour work-year and inflation, and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead, yielding an effective hourly rate of $2,944.

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.

Written comments are invited 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 collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O Cynthia Roscoe, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 4, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24844 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–824; OMB Control No. 3235–0500]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 608

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 608 (17 CFR 242.608) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 608 specifies procedures for filing or amending national market system plans (''NMS Plans''). Self-regulatory organizations (''SROs'') filing a new NMS Plan must submit the text of the NMS Plan to the Commission, along with a statement of purpose, and, if applicable, specified supporting materials that may include: (1) A copy of all governing or constituent documents, (2) a description of the manner in which the NMS Plan, and any facility or procedure contemplated by the NMS Plan, will be implemented, (3) a listing of all significant phases of development and implementation contemplated by the NMS Plan, including a projected completion date for each phase, (4) an analysis of the competitive impact of implementing the NMS Plan, (5) a description of any written agreements or understandings between or among plan participants or sponsors relating to interpretations of the NMS Plan or conditions for becoming a plan participant or sponsor, and (6) a description of the manner in which any facility contemplated by the NMS Plan shall be operated. Participants or sponsors to the NMS Plan must ensure that a current and complete version of the NMS Plan is posted on a designated website or a plan website after being notified by the Commission that the NMS Plan is effective. Each plan participant or sponsor must also provide a link on its own website to the current website to the current version of the NMS Plan.

The Commission estimates that the creation and submission of a new NMS Plan and any related materials would result in an average aggregate burden of approximately 850 hours per year (25 SROs × 34 hours = 850 hours). The Commission further estimates an average aggregate burden of approximately 125 hours per year (25 SROs × 5 hours = 125 hours), for each of the SROs to keep a current and complete version of the NMS Plan posted on a designated website or a plan website, and to provide a link to the current version of the NMS Plan on its own website. In addition, the Commission estimates that the creation of a new NMS Plan and any related materials would result in an average aggregate cost of approximately $150,000 per year (25 SROs × $6,000 = $150,000).

SROs proposing to amend an existing NMS Plan must submit the text of the amendment to the Commission, along with a statement of purpose, and, if applicable, the supporting materials described above, as well as a statement that the amendment has been approved by the plan participants or sponsors in accordance with the terms of the NMS Plan. Participants or sponsors to the NMS Plan must ensure that any proposed amendments are posted to a designated website or a plan website after filing the amendments with the Commission and that those websites are updated to reflect the current status of the amendment and the NMS Plan. Each plan participant or sponsor must also provide a link on its own website to the current version of the NMS Plan. The Commission estimates that the creation and submission of NMS Plan amendments and any related materials would result in an average aggregate burden of approximately 11,050 hours per year (25 SROs × 442 hours = 11,050 hours). The Commission further estimates an average aggregate burden of approximately 124 hours per year (25 SROs × 4.94 hours = 123.5 hours rounded up to 124) for SROs to post any pending NMS Plan amendments to a designated website or a plan website and to update such websites to reflect the current status of the amendment and the NMS Plan. In addition, the Commission estimates that the creation of a NMS Plan amendment and any related materials would result in an average aggregate cost of approximately $325,000 per year (25 SROs × $13,000 = $325,000).

Finally, to the extent that a plan processor is required for any facility contemplated by a NMS Plan, the plan participants or sponsors must file with the Commission a statement identifying the plan processor selected, describing the material terms under which the plan processor is to serve, and indicating the solicitation efforts, if any, for alternative plan processors, the alternatives considered, and the reasons for the selection of the plan processor. The Commission estimates that the preparation and materials related to the selection of a plan processor would result in an average aggregate burden of approximately 283 hours per year (25 SROs × 11.33 hours = 283.33 rounded down to 233). In addition, the Commission estimates that the preparation and submission of materials related to the selection of a plan processor would result in an average aggregate cost of approximately $8,333 per year (25 SROs × $333.33 = $8,333.33 rounded down to $8,333).

The above estimates result in a total annual industry burden of approximately 12,432 hours (850 + 125 + 11,050 + 124 + 283) and a total annual industry cost of approximately $483,333 ($150,000 + $325,000 + $8,333).

Compliance with Rule 608 is mandatory. The text of the NMS Plans and any amendments will not be confidential, but published on a designated website or a plan website. To the extent that Rule 608 requires the SROs to submit confidential information

to the Commission, that information will be kept confidential subject to the provisions of applicable law.[1] The SROs are required by law to retain the records and information that are collected pursuant to Rule 608 for a period of not less than 5 years, the first 2 years in an easily accessible place.[2] Rule 608 does not affect this existing requirement.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 4, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24840 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–423, OMB Control No. 3235–0472]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 15c1–6

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the existing collection of information provided for in Rule 15c1–6 (17 CFR 240.15c1–6) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 15c1–6 states that any broker-dealer trying to sell to or buy from a customer a security in a primary or secondary distribution in which the broker-dealer is participating or is otherwise financially interested must give the customer written notification of the broker-dealer's participation or interest at or before completion of the transaction. The Commission estimates that approximately 365 respondents will collect information annually under Rule 15c1–6 and that each respondent will spend approximately 10 hours annually complying with the collection of information requirement for a total burden of approximately 3,650 hours per year in the aggregate.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: November 4, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24842 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–422, OMB Control No. 3235–0471]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 15c1–5

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 15c1–5 (17 CFR 240.15c1–5) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 15c1–5 states that any broker-dealer controlled by, controlling, or under common control with the issuer of a security that the broker-dealer is trying to sell to or buy from a customer must give the customer written notification disclosing the control relationship at or before completion of the transaction. The Commission estimates that 181 respondents provide notifications annually under Rule 15c1–5 and that each respondent would spend approximately 10 hours per year complying with the requirements of the rule for a total burden of approximately 1,810 hours per year. There is no retention period requirement under Rule 15c1–5. This Rule does not involve the collection of confidential information.

Written comments are invited on: (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 estimates of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 4, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24841 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

[1] *See, e.g.,* 5 U.S.C. 552 *et seq.;* 15 U.S.C. 78x (governing the public availability of information obtained by the Commission).

[2] *See* 17 CFR 240.17a–1(b).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90328; File No. SR–NYSECHX–2020–26]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend the Exchange's Co-Location Services To Establish Procedures for the Allocation of Cabinets to Its Co-Located Users

November 3, 2020.

On September 2, 2020, NYSE Chicago, Inc. (''NYSE Chicago'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish procedures as part of the Exchange's co-location rules to allocate cabinets to its co-located users in situations where the Exchange cannot satisfy the user demand for cabinets. The proposed rule change was published for comment in the **Federal Register** on September 22, 2020.[3] The Commission received no comments on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 6, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates December 21, 2020, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSECHX–2020–26).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24790 Filed 11–6–20; 8:45 am]

BILLING CODE P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89886 (September 16, 2020) 85 FR 59582 (SR–NYSECHX–2020–26).

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90315; File No. SR–OCC–2020–013]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Proposed Rule Change To Update The Options Clearing Corporation's Recovery and Orderly Wind-Down Plan

November 3, 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 October 20, 2020, The Options Clearing Corporation (''OCC'') 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 primarily by OCC. 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

This proposed rule change by OCC would amend OCC's Recovery and Orderly Wind-Down Plan (''RWD Plan'' or ''Plan''), adopted pursuant to the requirement in Rule 17Ad–22(e)(3)(ii),[3] to reflect: (i) Changes to OCC's capital structure resulting from the disapproval of OCC's previously approved ''Capital Plan'' [4] and the subsequent approval of OCC's ''Capital Management Policy,'' [5] and (ii) changes made to each chapter of the Plan during OCC's annual internal review and update of the Plan, as required by OCC's internal governance.

The RWD Plan is included as confidential Exhibit 5 to SR–OCC–2020–013. Material proposed to be added is marked by underlining and material proposed to be deleted is marked by strikethrough text.[6] The proposed rule change does not require any changes to the text of OCC's By-Laws or Rules. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[7]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

Background

On August 23, 2018, the Commission approved OCC's proposed rule change to formalize and update OCC's RWD Plan, consistent with the requirements of Rule 17Ad–22(e)(3)(ii).[8] As approved, the RWD Plan incorporated key pieces of OCC's previously approved Capital Plan, including but not limited to the Capital Plan's provision for ''Replenishment Capital.'' [9] In OCC's RWD Plan, Replenishment Capital was one of the tools by which OCC could have recapitalized in certain of its recovery and wind-down scenarios.

On February 13, 2019, the Commission disapproved OCC's Capital Plan.[10] The disapproval of the Capital

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.17Ad–22(e)(3)(ii).

[4] Securities Exchange Act Release No. 85121 (Feb. 13, 2019), 84 FR 5157 (Feb. 20, 2019) (SR–OCC–2015–02).

[5] Securities Exchange Act Release No. 86725 (Aug. 21, 2019), 84 FR 44952 (Aug. 27, 2019) (SR–OCC–2019–007).

[6] OCC has also filed an advance notice with the Commission in connection with this proposal. *See* SR–OCC–2020–806.

[7] OCC's By-Laws and Rules can be found on OCC's public website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

[8] Securities Exchange Act Release No. 83918 (Aug. 23, 2018), 83 FR 44091 (Aug. 29, 2018) (SR–OCC–2017–021).

[9] Securities Exchange Act Release No. 74452 (Mar. 6, 2015), 80 FR 13058 (Mar. 12, 2015) (SR–OCC–2015–02). The Capital Plan was a previously approved plan for raising additional capital under which the securities options exchanges that own equity in OCC committed to contributing additional capital to OCC under certain conditions and provided for the provision of further Replenishment Capital in certain circumstances.

[10] *See* supra note 5.

Plan left OCC's RWD Plan with several invalid references to the Capital Plan or to certain of its component parts, including references to Replenishment Capital as one of OCC's identified tools for recovery and wind-down and references to a trigger event within the Capital Plan as one of OCC's recovery triggers. As a result of the disapproval of the Capital Plan, OCC subsequently proposed the ''Capital Management Policy,'' which among other things establishes a new mechanism for funding OCC's replenishment capital and changes OCC's ''default waterfall'' (*i.e.,* the resources available to OCC in the event of a Clearing Member's suspension).[11] These changes to OCC's replenishment capital and default waterfall necessitated changes to existing passages concerning the same in the RWD Plan.

In addition, OCC has made changes to its RWD Plan as a result of its annual review and update process. As adopted, the RWD Plan itself recognizes OCC's internal governance requirement to review and update the Plan at least every twelve months. Accordingly, during the first several months of 2019 and 2020, an internal, cross-disciplinary working group within OCC conducted a review and recommended numerous changes to the RWD Plan, which were approved by OCC's management, the Risk Committee of OCC's Board of Directors (''Board'') and OCC's Board. The changes resulting from the adoption of the Capital Management Policy and the changes from OCC's annual review process are discussed in greater detail below.

Proposed Changes

The proposed rule change would update each of the eight chapters of the RWD Plan.[12] A summary description of the types of changes proposed to each of the eight chapters of the RWD Plan is provided below:

Chapter 1: Executive Summary

Chapter 1 of the RWD Plan provides an executive summary and overview of OCC's proposed Plan. The proposed changes to Chapter 1 of the Plan would simply align the executive summary and overview to the changes made throughout subsequent chapters of the Plan.

Chapter 2: OCC Overview

Chapter 2 of the RWD Plan provides information that OCC believes would be essential to relevant authorities for purposes of recovery and orderly wind-down planning, as well as to provide readers of the Plan with necessary context for the subsequent discussion and analysis of OCC's ''Critical Services'' and ''Critical Support Functions'' in Chapter 4 (discussed below) and of OCC's wind-down process in Chapter 6 (discussed below). The proposed rule change would update several figures and factual discussions to reflect changes since the Plan's initial approval by the Commission. The types of changes being made to Chapter 2 would include: (i) Updated figures and numbers about market share and contract volume; (ii) updated lists of securities options exchanges and futures exchanges cleared by OCC; (iii) updated organizational charts, headcount numbers, discussions of OCC's management structure and descriptions of management roles and responsibilities; (iv) updated descriptions of OCC's Board's responsibilities and procedures, lists of Board members, and descriptions of OCC's Board committees' roles and responsibilities;[13] (v) revised descriptions that would acknowledge certain program changes that have occurred since the initial 2018 approval of the RWD Plan (*e.g.,* changes to OCC's cross-margining arrangements, changes in credit facilities and changes concerning investment counterparties, exchanges and vendors); (vi) updated graphs of OCC's Clearing Fund total monthly deposits; and (vii) updated discussions of OCC's retirement plan obligations. In addition to these updated figures and factual discussions, the proposed rule change would (i) revise Chapter 2 to remove excerpts from OCC's most recent annual report (which would be relocated to one of the appendices); (ii) replace a lengthy overview of OCC's risk management program with a more concise summary; (iii) update a summary description of OCC's interconnections with external vendors and a list of vendors that provide OCC critical technology and information reporting services; and (iv) revise a fee management discussion to align with changes resulting from the implementation of the Capital Management Policy.[14]

Chapter 3: Support Functions

Chapter 3 of the RWD Plan identifies each of OCC's different internal support functions and provides a brief description of the activities performed by each such support function. For purposes of the RWD Plan, ''internal support functions'' are the various departments within OCC that are necessary for OCC to provide its services to Clearing Members and other participants. Since the initial 2018 approval of the RWD Plan, OCC has added two additional internal support functions and expanded its Office of the Chief Executive Officer, renamed the ''Corporate'' support function, to include OCC's executive officers and administrative support staff. Accordingly, the proposed rule change would add two new internal support functions (and descriptions thereof) and replace the Office of the Chief Executive Officer with the Corporate support function, bringing the total number of internal support functions from 14 to 16. Since the initial 2018 approval of the RWD Plan, OCC also has modified and updated its administrative descriptions of the roles and responsibilities of the 14 internal support functions that were discussed in the initial 2018 approval of the RWD Plan. Accordingly, the proposed rule change would update the descriptions of all OCC's internal support functions so they align with the modified and updated internal administrative descriptions of such functions.

Chapter 4: Critical Services and Critical Support Functions

Chapter 4 of the RWD Plan identifies OCC's ''Critical Services'' [15] and ''Critical Support Functions.'' [16] The proposed rule change would group two previously identified Critical Services into a single Critical Service (*i.e.,* the changes would simply use a single term to refer to two services that were previously listed separately). The proposed rule change also would update dated factual references and make other minor changes to OCC's description of its evaluations of Critical Services and Critical Support Functions, notably to recognize the consolidation of the two previously identified Critical Services

[11] *See* supra note 6.

[12] In addition to the changes summarized below, OCC would also make administrative changes throughout the Plan to update various OCC internal policy and procedure names.

[13] Securities Exchange Act Release No. 84473 (Oct. 23, 2018), 83 FR 54385 (Oct. 29, 2018) (SR–OCC–2018–012).

[14] The changes to the fee management discussion concern the potential for OCC's Board to lower the direct costs of participation if OCC's shareholder equity exceeds 110% of a predetermined ''Target Capital Requirement.'' *See* Securities Exchange Act Release No. 86725 (Aug. 21, 2019), 84 FR 44944 (Aug. 27, 2019) (SR–OCC–2019–007).

[15] A ''Critical Service,'' as defined in the proposed Plan, would be a service provided by OCC that, if interrupted, would likely have a material negative impact on participants or significant third parties, give rise to contagion, or undermine the general confidence of markets the FMU serves.

[16] A ''Critical Support Function,'' as defined in the proposed Plan, would be a function within OCC that must continue in some capacity in order for OCC to be able to continue providing its Critical Services.

into a single Critical Service and recalibrate the evaluation of an OCC service in considering whether it is a Critical Service. The proposed rule change also would change the mapping of Critical Services to Support Functions to recognize the ''primary,'' ''secondary,'' or ''non-critical'' nature of each Support Function, which better aligns with OCC's internal taxonomy.

Chapter 5: Recovery Plan

Chapter 5 of OCC's proposed Plan constitutes OCC's recovery plan. The proposed rule change would make conforming edits to references to certain former provisions within OCC's By-Laws that have since been relocated to OCC's Rules.[17] The proposed rule change also would revise the inventory and description of OCC's available ''Enhanced Risk Management Tools'' and ''Recovery Tools'' to (i) replace references to and discussions of Replenishment Capital with references to and descriptions of the replenishment structure under the adopted Capital Management Policy; (ii) replace references to and discussions of the discretionary use of OCC's current and/or retained earnings with references to and discussions of the mandatory contribution—immediately following the use of margin, deposits in lieu of margin and the Clearing Fund deposits of the suspended Clearing Member—of OCC's current and retained earnings greater than 110% of OCC's annually-established ''Target Capital Requirement,'' as implemented by the Capital Management Policy; (iii) update the description of how OCC could increase the minimum required cash contribution to the Clearing Fund to reflect enhancements to OCC's liquidity risk management framework that the Commission approved in 2020;[18] (iv) include a discussion of the mandatory contribution of any unvested portions of OCC's Executive Deferred Compensation Plan (''EDCP''), in proportion to any charges against the mutualized portion of OCC's Clearing Fund, as implemented by the Capital Management Policy; and (v) update the governance of the Recovery Tools to include OCC's Chief Executive Officer and Chief Operating Officer in various communications to OCC's Executive Chairman. The proposed rule change also would revise the list of ''Recovery Trigger Events'' in the recovery plan to (i) delete one of the Recovery Trigger Events that was derived from a defined term in the Capital Plan, (ii) consolidate two other Recovery Trigger Events into a single, operational loss-related recovery trigger, and (iii) add a qualification onto an existing liquidity loss-related recovery trigger. The proposed rule change would also delete unnecessary historical data on business volumes from the hypothetical stress scenarios in Chapter 5 that illustrate how OCC could use its recovery tools.

Chapter 6: Wind-Down Plan

Chapter 6 of OCC's RWD Plan constitutes OCC's orderly wind-down plan. The proposed rule change would revise the list of Wind-Down Plan Trigger Events (''WDP Triggers'') to consolidate two current WDP Triggers into a single WDP Trigger related to OCC's financial resource requirements, and consolidate two other current WDP Triggers into a single WDP Trigger related to operational disruption. The proposed rule change would also update discussions of the tools by which OCC could have recapitalized in certain of its recovery and wind-down scenarios. As revised, these discussions would describe replenishment capital available under the adopted Capital Management Policy, deleting descriptions of Replenishment Capital available under the former Capital Plan. The proposed rule change also would update certain of the references to OCC's internal support functions and certain references to headcount in Chapter 6.

Chapter 7: RWD Plan Governance

Chapter 7 of OCC's RWD Plan section details the governance of OCC's RWD Plan. The proposed rule change would revise the lists of OCC staff involved in the completion of the plan (largely to give effect to the fact that the titles of certain offices changed since the RWD Plan's proposal in 2017).

Chapter 8: Appendices

Chapter 8 of OCC's RWD Plan is comprised of several appendices. The proposed rule change would update several lists within the appendices to reflect changes that have occurred since the Plan's initial approval by the Commission. The types of changes being made to Chapter 8 would include: (i) Updated lists of OCC's clearing membership; (ii) updated lists of participation on OCC's Board; (iii) updated lists of settlement banks and letter of credit banks; (iv) updated lists of vendors and service providers that would be necessary to support a recovery or wind-down of OCC; (v) updates to the extreme hypothetical scenarios designed by OCC that, if such scenarios occurred, could cause OCC to activate the RWD Plan; and (vi) updated lists of the key agreements to be maintained during recovery and wind-down efforts.

(2) Statutory Basis

OCC believes that the proposed rule change is consistent with Section 17A of the Act[19] and the rules thereunder applicable to OCC. Section 17A(b)(3)(F) of the Act[20] requires, in part, that the rules of a clearing agency be designed, in general, to protect investors and the public interest. The RWD Plan is designed to enhance OCC's ability to address extreme stresses or crises by establishing a framework that OCC could use to navigate the use its Enhanced Risk Management Tools and Recovery Tools, with the aim of maintaining OCC's viability as a going concern. In the event that OCC's recovery efforts are not successful, the RWD Plan would seek to improve the possibility that a resolution of OCC's operations can be conducted in an orderly manner, thereby minimizing the disruption to Clearing Members and market participants and improving the likelihood of minimizing the risk of contagion to the broader financial system. Accordingly, OCC believes the conforming updates to the RWD Plan would improve the possibility of OCC's effectively addressing a variety of potential risks, thereby improving OCC's ability to ultimately maintain market and public confidence during a time of unprecedented stress. In this regard, OCC believes the proposed rule change ultimately would protect investors and the public interest in a manner consistent with Section 17A(b)(3)(F) of the Act.[21]

OCC also believes that the proposed rule change is consistent with Exchange Act Rule 17Ad–22(e)(3)(ii), which requires each covered clearing agency to establish, implement, maintain and enforce written policies and procedures reasonably designed to include plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses.[22] As stated above, the RWD Plan would describe OCC's plans to recover from, or orderly resolve its operations as a result of, severe stress brought about by credit losses, liquidity shortfalls, losses from general business risk or other losses.[23] The proposed

[17] *See* Securities Exchange Act Release No. 83735 (Jul. 27, 2018), 83 FR 37855 (Aug. 2, 2018) (SR–OCC–2010–008).

[18] *See* Securities Exchange Act Release No. 89014 (Jun. 4, 2020), 85 FR 35446 (Jun. 10, 2020) (SR–OCC–2020–003).

[19] 15 U.S.C. 78q–1.

[20] 15 U.S.C. 78q–1(b)(3)(F).

[21] 15 U.S.C. 78q–1(b)(3)(F).

[22] 17 CFR 240.17Ad–22(e)(3)(ii).

[23] 17 CFR 240.17Ad–22(e)(3)(ii).

updates to the RWD Plan would improve the accuracy of the inventory of OCC's Recovery Tools and improve OCC's evaluation of scenarios which may potentially prevent OCC from providing its Critical Services as a going-concern, as well as OCC's plans for recovery or orderly wind-down. Further, the proposed changes to the Plan would update and improve the information that a resolution authority may reasonably anticipate as necessary for purposes of recovery and orderly wind-down planning.[24] In this regard, OCC believes its proposed rule change is consistent with Rule 17Ad–22(e)(3)(ii).[25]

The proposed rule change is not inconsistent with the existing rules of OCC, including any other rules proposed to be amended.

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act [26] requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. OCC does not believe that the proposed rule change would impact or impose any burden on competition.[27] The proposed rule change would update OCC's RWD Plan. The proposed updates to the RWD Plan are the result of OCC's annual review and update process; these proposed changes would revise certain factual representations, update certain organizational discussion and make changes to conform to OCC's adopted Capital Management Policy. None of the proposed updates to the RWD Plan would affect Clearing Members' access to OCC's services or impose any direct burdens on clearing members. Accordingly, the proposed rule change would not unfairly inhibit access to OCC's services or disadvantage or favor any particular user in relationship to another user.

For the foregoing reasons, OCC believes that the proposed rule change is in the public interest, would be consistent with the requirements of the Act applicable to clearing agencies, and would not impact or impose a burden on competition.

[24] *See* 81 FR at 70810.

[25] 17 CFR 240.17Ad–22(e)(3)(ii).

[26] 15 U.S.C. 78q–1(b)(3)(I).

[27] 15 U.S.C. 78q–1(b)(3)(I).

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

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 the 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–OCC–2020–013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2020–013. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

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–OCC–2020–013 and should be submitted on or before November 30, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24783 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90324; File No. SR–FINRA–2020–037]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change To Amend the By-Laws of FINRA Regulation, Inc. To Align the Grounds for Member Removal From the NAC With an Existing Provision in the FINRA By-Laws

November 3, 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 October 22, 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

[28] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend the By-Laws of FINRA Regulation, Inc. (''FINRA Regulation''), FINRA's regulatory subsidiary, to further align the grounds for member removal from the National Adjudicatory Council (''NAC'') with an existing provision in the FINRA By-Laws related to the removal of a FINRA Governor from the FINRA Board of Governors (''FINRA Board'').[3]

Below is the text of the proposed rule change. Proposed new language is italicized.

* * * * *

BY–LAWS OF FINRA REGULATION, INC.

* * * * *

ARTICLE V NATIONAL ADJUDICATORY COUNCIL

* * * * *

Removal

Sec. 5.8 Any or all of the members of the National Adjudicatory Council may be removed from office at any time for refusal, failure, neglect, or inability to discharge the duties of such office, *or for any cause affecting the best interests of the National Adjudicatory Council the sufficiency of which the FINRA Board shall be the sole judge,* by majority vote of the FINRA Board.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA Regulation is the regulatory subsidiary of FINRA and operates according to the Plan of Allocation and Delegation of Functions by FINRA to Subsidiaries (the ''Plan'').[4] The FINRA Regulation By-Laws authorize the NAC to function on behalf of the FINRA Board in several capacities.[5] For example, the NAC presides over disciplinary matters appealed to or called for review by the NAC; acts on applications in statutory disqualification and membership proceedings; exercises exemptive authority; and acts in other proceedings as set forth in the FINRA Rule 9000 Series (Code of Procedure). The FINRA Board may also delegate other powers and duties to the NAC as the FINRA Board deems appropriate and in a manner not inconsistent with the Plan.[6] For most matters that the NAC considers, the NAC prepares proposed written decisions that become final FINRA action if the FINRA Board does not call them for review.

FINRA periodically reviews its and FINRA Regulation's By-Laws to ensure adherence to effective governance practices. The FINRA Regulation By-Laws currently permit the FINRA Board to remove ''any or all members'' of the NAC from office at any time for refusal, failure, neglect, or inability to discharge the duties of the office.[7] By comparison, the FINRA By-Laws include those grounds for removal of a Governor from the FINRA Board plus an additional ground allowing for removal for any cause affecting the best interests of FINRA the sufficiency of which the FINRA Board shall be the sole judge.[8] The proposed rule change would amend Article V, Section 5.8 of the FINRA Regulation By-Laws to align the bases for removal of a member of the NAC in the FINRA Regulation By-Laws with those of the FINRA By-Laws for removal of a Governor. Specifically, the proposed rule change would provide that a NAC member could be removed by a majority vote of the FINRA Board for any cause affecting the best interests of the NAC, the sufficiency of which the FINRA Board shall be the sole judge.

FINRA notes that the voting threshold for removal of a NAC member differs from that of a Governor. The former requires a majority vote of the FINRA Board, while the latter requires a two-thirds vote.[9] The higher voting threshold for removal of a Governor reflects the historical standard that existed at the National Association of Securities Dealers (''NASD'') prior to its 2007 merger with the member regulation, enforcement and arbitration operations of the New York Stock Exchange (''NYSE'') that formed FINRA, and provides an additional safeguard at the FINRA Board level to ensure a diverse, majority non-industry composition, and fair representation of the industry in governance matters.[10]

Given the NAC's adjudicatory role, the best interests of the NAC are more targeted than the best interests of FINRA. The best interests of the NAC are reflected in conduct and attributes that ensure that the NAC remains an unbiased and competent adjudicatory body that is free of conflicts of interest, that its members conduct themselves with integrity, and that its decisions are rendered fairly and consistently with the law and rules that govern FINRA members and their associated persons. In considering whether to remove a NAC member for a cause affecting the best interests of the NAC, the FINRA Board may consider, among other things, a NAC member's adherence to general standards concerning actual and apparent adjudicator conflicts of interest and bias,[11] and to the NAC's Conflict of Interest and Bias Policy (''Policy''). The Policy sets forth broad-based principles of behavior that are expected from NAC members.[12] Removal of a NAC member

[3] In 2008, the FINRA Regulation By-Laws were amended to, among other things, designate the FINRA Board as the body authorized to oversee the NAC and empowered to remove NAC members for refusal, failure, neglect, or inability to discharge duties. *See* Securities Exchange Act Release No. 58909 (November 6, 2008), 73 FR 68467 (November 18, 2008) (Order Approving File No. SR–FINRA–2008–046). Under the FINRA By-Laws, members of the FINRA Board can be removed under the same grounds, plus an additional ground. *See infra* note 8.

[4] *See* Plan, II. FINRA Regulation, Inc., *https://www.finra.org/rules-guidance/rulebooks/corporate-organization/ii-finra-regulation-inc.*

[5] *See* Article V, Sec. 5.1 of the FINRA Regulation By-Laws.

[6] *See supra* note 5.

[7] *See* Article V, Section 5.8 of the FINRA Regulation By-Laws.

[8] *See* Article VII, Section 1(b) of the FINRA By-Laws.

[9] Both FINRA and FINRA Regulation are corporations organized under Delaware law. The Delaware General Corporation Law provides that, in general, directors may be removed by a majority vote of the shares then entitled to vote at an election of directors. *See* Del. Code Ann. tit. 8, § 141(k). While the standard for removal of NAC members is not directly subject to the Delaware General Corporation Law, FINRA has adopted a removal threshold for NAC members that is consistent with the removal threshold for directors under the Delaware Corporation Law.

[10] The FINRA Regulation By-Laws addressing the composition of the NAC also provide for a diverse, majority non-industry composition, and for the fair representation of industry. *See* Article V, Section 5.2(a) of the FINRA Regulation By-Laws; *See also* Securities Exchange Act Release No. 78094 (June 17, 2016), 81 FR 40932, 40934–35 (June 23, 2016).

[11] *See, e.g.,* Article IV, Section 4.14(a) of the FINRA Regulation By-Laws.

[12] The principles outlined in the Policy are Independence, Impartiality, Integrity, Accountability and Transparency; and place upon NAC adjudicators the responsibility for recognizing and reporting actual and apparent conflicts of interest and bias.

from office is a facts and circumstances determination. The additional removal authority provided in the proposed rule change may, depending on the facts and circumstances, overlap in part with the FINRA Board's existing authority to remove a NAC member. However, depending on the facts and circumstances, it may also provide an additional basis for removal for a cause affecting the best interests of the NAC that does not fall within the scope of the FINRA Board's current removal authority.

In order to balance the NAC's ability to perform certain actions on behalf of FINRA [13] with the FINRA Board's authority to review such actions,[14] FINRA believes that it is reasonable and appropriate to amend the FINRA Regulation By-Laws to align the grounds under which members of the NAC and FINRA Board can be removed. In doing so, the proposed rule change will strengthen the FINRA Board's oversight of the NAC and benefit the appellate portion of FINRA's disciplinary process, in which the NAC prepares the decision that becomes FINRA's final action in the vast majority of cases.

If the Commission approves the proposed rule change, the effective date of the proposed rule change will be the date of Commission approval.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[15] 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; and Section 15A(b)(4) of the Act, which requires, among other things, that FINRA rules be designed to assure a fair representation of FINRA's members in the administration of its affairs.[16] FINRA believes that the proposed By-Laws change will strengthen its governance practices by aligning grounds for removal of NAC members with those of the FINRA Governors. The FINRA By-Law provision that allows for the Board's direct ability to remove a Governor for any cause affecting the best interests of FINRA existed in the By-Laws of the NASD prior to its 2007 merger with the NYSE, and was also a part of the By-Laws that were previously found to meet the statutory requirement when the NASD merged with the member regulation, enforcement and arbitration operations of the NYSE to form FINRA.[17] FINRA also believes applying the same standard to removal of NAC members will support a fair and impartial disciplinary process for members and their associated persons. FINRA further believes that the proposed rule change will strengthen investor protection and further the public interest by bolstering the integrity of the NAC and strengthening existing FINRA Regulation By-Laws that foster a framework in which NAC members may perform their duties free from bias or conflicts of interest. In addition, FINRA believes that the proposed rule change furthers FINRA's ability to assure a fair representation of FINRA members on the NAC by enhancing the FINRA Board's ability to remove NAC members for conduct that might hamper the NAC's adjudicatory function.

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 evaluated the potential for economic impacts associated with the proposed rule change and determined that no material costs or benefits were likely to arise. The proposed rule change would not require member firms or other persons appearing before the NAC to incur any direct costs or change their behaviors in any way. All potential actions taken pursuant to the proposed rule change would be taken by the FINRA Board. Further, FINRA's other By-Law provisions remain unchanged, so the proposed rule change will have no material impact on fair process to litigants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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–2020–037 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–2020–037. 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 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

[13] *See supra* note 5.

[14] *See* Plan, I(B). FINRA, Inc., *https://www.finra.org/rules-guidance/rulebooks/corporate-organization/i-finra-inc.*

[15] 15 U.S.C. 78*o*–3(b)(6).

[16] 15 U.S.C. 78*o*–3(b)(4).

[17] *See* Securities Exchange Act Release No. 56145 (July 26, 2007), 72 FR 42169 (August 1, 2007), as amended by Securities Exchange Act Release No. 56145A (May 30, 2008), 73 FR 32377 (June 6, 2008) (Order Approving File No. SR–NASD–2007–023).

submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2020–037 and should be submitted on or before November 30, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–24787 Filed 11–6–20; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 8, 2021.

ADDRESSES: Send all comments to, Kelly Templeton Financial Analyst, Office of Portfolio Management and Office of Financial Program Operations, Small Business Administration, 409 3rd Street, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Kelly Templeton, Financial Analyst Office of Portfolio Management and Office of Financial Program Operations *Kelly.templeton@sba.gov* Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: Lenders requesting SBA to purchase the guaranty portion of a loan are required to supply the Agency with a certified transcript of the loan account. This form is uniform and convenient means for lenders to report and certify loan accounts to purchase by SBA. The Agency uses the information to determine date of loan default and whether Lender disbursed and serviced the loan according to Loan Guaranty agreement.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

(1) Title: Lender's Transcript of Account.

Description of Respondents: SBA Lenders.

Form Number: SBA Form 1149.

Total Estimated Annual Responses: 3,600.

Total Estimated Annual Hour Burden: 36,000.

Curtis Rich,

Management Analyst.

[FR Doc. 2020–24764 Filed 11–6–20; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 8, 2021.

ADDRESSES: Send all comments to, Susan Streich, Director, Office of Credit Risk Management, Small Business Administration, 409 3rd Street, 7th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Susan Streich, Director, Office of Credit Risk Management 202–205–6641, *susan.streich@sba.gov* or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: Small Business Lending Companies (SBLCs) and Non-federally regulated lenders (NFRLs). NFRL'S are non-depository lending institutions authorized by SBA primarily to make loans under section 7(a) of the Small Business Act. As sole regulator of these institutions, SBA requires them to submit audited financial statements annually as well as interim, quarterly financial statements and other reports to facilitate the Agency's oversight of these lenders.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

Collection: 3245–0077.

Title of Collection: Reports to SBA Provisions of 13 CFR 120.464.

Description of Respondents: Small Business Lending Companies (SBLCs) and Non-federally regulated lenders (NFRLs).

Total Estimated Annual Responses: 594.

Total Estimated Annual Hour Burden: 7,110.

Curtis Rich,

Management Analyst.

[FR Doc. 2020–24770 Filed 11–6–20; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice 11246]

30-Day Notice of Proposed Information Collection: Individual, Corporate or Foundation, and Government Donor Letter Applications

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to December 9, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent

within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Chanel Wallace 2201 C Street NW, Room 1821, Washington, DC 20520, who may be reached on (202) 647–7730 or at *WallaceCR2@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Individual, Corporate or Foundation and Government Donor Letter Application.
- *OMB Control Number:* 1405–0218.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Office of Emergencies in the Diplomatic and Consular Service (EDCS).
- *Form Number:* Donor Form—Individual (DS–4273), Donor Form—Corporate or Foundation (DS–4272), Donor Form—Government (DS–4271).
- *Respondents:* Individuals, Corporations, or Foundations that make donations to the Department.
- *Estimated Number of Respondents:* 4,079.
- *Estimated Number of Responses:* 4,079.
- *Average Time per Response:* 10 minutes per response.
- *Total Estimated Burden Time:* 680 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- 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.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Office of Emergencies in the Diplomatic and Consular Service (EDCS) manages the solicitation and acceptance of gifts to the U.S. Department of State. The information requested via donor letters is a necessary first step to accepting donations. The information is sought pursuant to 22 U.S.C. 2697, 5 U.S.C. 7324 and 22 CFR, Part 3) and will be used by EDCS's Gift Fund Coordinator to demonstrate the donor's intention to donate either an in-kind or monetary gift to the Department. This information is mandatory and must be completed before the gift is received by the Department.

Methodology

The information collection forms will be available to program offices who have authority to solicit or accept donations on behalf of the Department. Donors can also request and complete hard copies of the form if internet access is not available. After completion, all forms are mailed to EDCS.

Crystal F. Jobe,

Gift Funds and K Funds Coordinator.

[FR Doc. 2020–24775 Filed 11–6–20; 8:45 am]

BILLING CODE 4710–37–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2020–0019]

Results of the 2020 Annual Generalized System of Preferences (GSP) Review

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is announcing the results of the 2020 Annual GSP Review with respect to: Products considered for the addition to, and removal from, the list of eligible products for certain beneficiary countries; and decisions related to competitive need limitations (CNLs), including petitions for waivers of CNLs.

FOR FURTHER INFORMATION CONTACT: Claudia Chlebek, Director for GSP at (202) 395–2974 or *claudia.m.chlebek@ustr.eop.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The GSP program provides for the duty-free treatment of designated articles when imported from beneficiary developing countries. The GSP program is authorized by Title V of the Trade Act of 1974 (19 U.S.C. 2461 *et seq.*), as amended, and is implemented in accordance with Executive Order 11888 of November 24, 1975, as modified by subsequent Executive Orders and Presidential Proclamations.

Each year, USTR leads the interagency Trade Policy Staff Committee (TPSC) GSP Subcommittee in reviewing the list of products eligible for GSP benefits and, after the completion of this process, which includes public hearings, provides recommendations to the President on appropriate actions based on statutory criteria, including exclusions from duty-free treatment of products from certain countries when they have reached the statutory CNL thresholds.

The GSP statute (19 U.S.C. 2463(c)(2)) establishes CNLs as a basis for withdrawing duty-free treatment. The statute provides that, when the President determines that a GSP beneficiary has exported to the United States during any calendar year a quantity of an eligible article that is either (1) greater than a specified amount ($190 million for 2019), or (2) exceeds 50 percent of the appraised value of the total U.S. imports of that article, the President ''shall, not later than November 1 of the next calendar year, terminate the duty-free treatment for that article'' from that beneficiary, unless a waiver is granted.

Under 19 U.S.C. 2463(d), the President may waive either CNL if, before November 1 of the calendar year following the year in which imports exceeded CNLs, the President (1) receives advice from the U.S. International Trade Commission on whether any industry in the United States is ''likely to be adversely affected by such waiver,'' (2) determines, based on certain statutory considerations, that such a waiver is in the national economic interest, and (3) publishes that determination in the **Federal Register**. The statute further provides in 19 U.S.C. 2363(c)(2)(F) that the President may disregard the 50 percent CNL if total imports of an article did not exceed a *de minimis* amount ($24.5 million in 2019), or if the product was not produced in the United States in any of the three preceding calendar years.

B. Results of the 2020 Annual GSP Review

In the 2020 Annual GSP Review, the TPSC reviewed (1) petitions to add fresh-cut roses to the list of products eligible for GSP, (2) a petition to remove

the GSP eligibility of 6 rice products, and (3) 24 products eligible for one-year *de minimis* waivers of CNLs.

Presidential Proclamation 10107 of October 30, 2020, implements the President's decisions regarding the 2020 Annual GSP Review, including product addition, product removal, and *de minimis* CNL waivers. These modifications to the GSP program became effective on November 1, 2020. This notice provides a summary of the results of the 2020 Annual GSP Review. You also can view the results, comprising four lists, at *https://www.regulations.gov* using docket number USTR–2020–0019, under ''Supporting and Related Materials'' and on the USTR website at *https://ustr.gov/sites/default/files/files/Press/Releases/GSP%20Annual%20Product%20Review%20-%20Final%20Decisions.pdf.*

As described in List I, the President granted the petitions to add fresh-cut roses (HTS 0603.11.00) to the list of GSP eligible products for all Beneficiary Developing Countries (BDCs). Therefore, qualifying products now enter the United States duty-free.

As described in List II, the President granted the petition to remove rice, semi-milled or wholly milled, whether or not polished or glazed, parboiled (HTS 1006.30.10) from GSP eligibility for all BDCs. Therefore, this product now is subject to the U.S. normal trade relations (NTR) duty rate.

As described in List III, the President granted one-year *de minimis* waivers to 24 products that exceeded the 50 percent import-share CNL but for which the aggregate value of all U.S. imports of that article was below the 2019 *de minimis* level of $24.5 million. Qualifying products will continue to enter the United States duty-free.

As described in List IV, six products exceeded the CNLs. For more information regarding petitions concerning CNLs, see 85 FR 27261 at *https://www.govinfo.gov/content/pkg/FR-2020-05-07/pdf/2020-09781.pdf.* These products now enter the United States at the NTR duty rate.

Laura Buffo,

Deputy Assistant U.S. Trade Representative for the Generalized System of Preferences, Office of the United States Trade Representative.

[FR Doc. 2020–24824 Filed 11–6–20; 8:45 am]

BILLING CODE 3290–F0–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0084; Notice 1]

Daimler Coaches North America, LLC, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Daimler Coaches North America, LLC (DCNA), a subsidiary of Daimler AG, has determined that certain model year (MY) 2012–2019 Setra S407 and MY 2009–2020 Setra S417 buses do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays.* DCNA filed a noncompliance report dated July 16, 2020. DCNA subsequently petitioned NHTSA on August 4, 2020, and later amended it on October 1, 2020, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces receipt of DCNA's petition.

DATES: Send comments on or before December 9, 2020.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the docket. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. Overview

DCNA has determined that certain MY 2012–2019 S407 and 2009–2020 Setra S417 buses do not fully comply with the requirements of paragraphs S.5.3.2.1 and S5.3.2.2 of Table 1 of FMVSS No. 101, *Controls and Displays* (49 CFR 571.101). DCNA filed a noncompliance report dated July 16, 2020, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* DCNA subsequently petitioned NHTSA on August 4, 2020, and later amended it petition on October 1, 2020, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

This notice of receipt of DCNA's petition is published under 49 U.S.C. 30118 and 30120 and does not represent

any Agency decision or other exercise of judgment concerning the merits of the petition.

II. Buses Involved

Approximately 538 MY 2012–2019 Setra S407 and MY 2009–2020 Setra S417 motorcoach buses manufactured between May 19, 2009, and December 18, 2019, are potentially involved.

III. Noncompliance

DCNA explains that the noncompliance is that the windshield defogging/defrosting and the hazard warning signal indicators in the subject buses do not meet the brightness of illumination requirements provided in paragraphs S5.3.2.1 and S5.3.2.2(a) of FMVSS No. 101. Specifically, the brightness of the windshield defogging/defrosting indicator cannot be adjusted and the hazard warning signal indicator does not illuminate.

IV. Rule Requirements

Paragraphs S.5.3.2.1 and S.5.3.2.2(a) of FMVSS No. 101 include the requirements relevant to this petition. Means must be provided for illuminating the indicators, identification of indicators, and identifications of controls listed in Table 1 to make them visible to the driver under daylight and nighttime driving conditions. The means of providing the visibility required by paragraph S5.3.2.1 must be adjustable to provide at least two levels of brightness.

V. Summary of DCNA's Petition

The following views and arguments presented in this section, ''V. Summary of DCNA's Petition,'' are the views and arguments provided by DCNA. They have not been evaluated by the Agency and do not reflect the views of the Agency. DCNA described the subject noncompliance and contended that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, which is attached in full to the docket, DCNA submitted the following reasoning:

1. DCNA explained its understanding of FMVSS No. 101 and described its opinion that the specified noncompliance does not increase risk to motor vehicle safety: FMVSS No. 101, *Controls and Displays,* is premised on ensuring the various controls, telltales, and indicators can easily be recognized in order to facilitate the driver's selection under day and nighttime conditions, to prevent the mistaken selection of controls and to reduce potential safety hazards when the driver's attention is diverted from the driving task. FMVSS No. 101 sets requirements for the location (S5.1), identification (S5.2), and illumination (S5.3) of various controls and displays, and Table 1 of the standard sets out those controls, telltales, and indicators with illumination and color requirements. At S5.3.1(b), the controls 1isted in Table 1 of the standard, including those for the hazard and windshield defrost/defog control, are required to be illuminated whenever the headlamps are activated, and the brightness of the control is to be adjustable to at least two levels.

DCNA believes that the lack of illumination on the hazard warning lamp symbol included on the control and inability to adjust the brightness of the defrost/defog control does not present an increased risk to motor vehicle safety. DCNA states that each of the controls is fully operable, and their function is not affected by the lack of illumination or ability to adjust the brightness of the individual control or identifier.

2. DCNA described the operation and design of the hazard warning lamp control for the subject vehicle and DCNA's assessment of risk: The hazard warning lamp is controlled by a large red plastic toggle switch that is 19 mm across by 40 mm high. The switch is activated by pressing the bottom half of the switch downward with one finger until a clicking noise occurs. When the hazard warning lamp is activated, even without illumination the operation of the hazard function is confirmed because the hazard lamp itself will flash on and off and both the right and left turn signal indicators in the instrument cluster will flash on and off and in unison with the hazard warning lamps on the exterior of the vehicle. Thus, there is no question that the driver would not be able to confirm that the hazard warning lamp is operational.

The vehicle operator can readily identify and locate the hazard warning lamp switch under nighttime conditions, even without the illumination of the hazard warning lamp symbol on the switch. The hazard warning lamp control is located at the immediate right of the driver. The switch is located at the driver's eye level and remains in plain view of the driver when the driver is belted. The hazard warning lamp switch is bright red and is the only switch or control on the immediate right side of the driver that is not black or grey and, thus, easily contrasts with the remainder of the interior and background of the driver's compartment area. The characteristics and placement of the hazard warning lamp switch make it readily apparent under all operating conditions.

3. DCNA described the operation and design of the windshield defrost/defog control for the subject vehicle and DCNA's assessment of risk: The windshield defrost/defog symbol is located adjacent to the control knob. The turn-style control knob that activates the windshield defrost/defog function and the adjacent symbol are automatically illuminated when the vehicle's headlamps are activated but cannot be dimmed in accordance with paragraph S5.3.2.1. However, each of the functions surrounding the windshield defrost/defog symbol, many of which are not regulated by FMVSS No. 101, Table 1, are illuminated. There is a master switch for adjusting the brightness of the area surrounding the driver. Dimming is controlled within the meter assembly menu for the dashboard lights and is adjustable to more than two different levels of brightness. Further, the windshield defog/defrost control is located within a group of controls that are responsible for the heating, cooling, and temperature operations of the driver's compartment of the vehicle. Therefore, the driver would be well aware of the location of the defrost/defog control because it is located within a cluster of controls that operate similar functions. Thus, there is little to no risk that the driver's vision would otherwise be impaired if the display was too bright or too dim.

Further, any driver of a motorcoach such as the vehicles that are the subject of this petition would be a professionally trained driver. As such, the driver would likely have experience in operating the particular vehicle and would be knowledgeable about the location and function of all of the controls and devices within the vehicle. More so, the interior cabin of the motorcoach in the area forward of the driver's seat is sufficiently lit by roadway lighting, other illuminated controls, telltales, and the light emitted from the display of the instrument cluster. As described above, the dashboard lamps are illuminated when the vehicle is operated with the headlamps on. This would also brighten the area in the vicinity of the driver and would assist in illuminating the hazard warning lamp and other controls and indicators.

The Agency has previously considered conditions where certain controls, telltales, and indicators listed in Table 1 were not visible to the driver under all day and night driving conditions and has concluded that the noncompliance is inconsequential. In particular, an electrical condition which could cause the headlamp upper beam indicator telltale to extinguish for

various periods of time and under certain conditions was deemed to be inconsequential. In granting the petition, the Agency relied on the fact that the upper beam telltale would only need to be illuminated under nighttime driving conditions and found at that time that ''a comparatively small portion of driving occurs at night, the time of headlamp activation.'' *See* Grant of Petition for Determination of Inconsequential Noncompliance, General Motors Corp., 56 FR 33323 (July 19, 1991).

The buses that are the subject of this petition are motor coaches largely used in commercial activity. As such, the drivers operating these vehicles are trained drivers that should be familiar with the layout, placement, and operation of the hazard warning lamp and defog/defrost controls. NHTSA has previously found that when trained drivers operate vehicles, this diminishes the potential safety consequence of an FMVSS No.101 noncompliance because it is expected that the drivers will not only monitor their vehicles' condition closely to ensure the systems are properly operating but that ''professional drivers will become familiar with the meaning of the telltales and other warnings and the feedback provided to the driver in these vehicles.'' *See* Mack Trucks, Inc., and Volvo Trucks North America, Grant of Petitions for Decision of Inconsequential Noncompliance, 84 FR 67766 (December 11, 2019); Autocar Industries, LLC, and Hino Motors Sales U.S.A., Inc., Grant of Petitions for Decision of Inconsequential Noncompliance, 84 FR 11162 (March 25, 2019); Daimler Trucks North America, LLC, Grant of Petition for Decision of Inconsequential Noncompliance, 82 FR 33551 (July 20, 2017).

4. DCNA summarized corrections taken and its lack of complaints or reports related to the condition described in the petition: Evo Bus and DCNA have corrected this issue in production by including a mechanism to adjust the brightness of the vehicle's defrost/defog control and to illuminate the hazard warning lamp control. DCNA is not aware of any complaints or reports related to the condition described in this petition. In the majority of cases, the vehicles have been in use for many years and without incident.

DCNA concluded by again contending that the subject noncompliances are inconsequential as they relate to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

DCNA's complete petition and all supporting documents are available by logging onto the Federal Docket Management System (FDMS) website at: *https://www.regulations.gov* and following the online search instructions to locate the docket number listed in the title of this notice.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject buses that DCNA no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant buses under their control after DCNA notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2020–24822 Filed 11–6–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Bureau of Engraving and Printing

Draft Environmental Impact Statement (EIS) and Draft Finding of No Practicable Alternative (FONPA) for the Proposed Construction and Operation of a Replacement Currency Production Facility at the Beltsville Agricultural Research Center, Prince George's County, MD

AGENCY: Bureau of Engraving and Printing, Department of the Treasury.

ACTION: Notice of availability (NOA).

SUMMARY: The U.S. Department of the Treasury (Treasury), Bureau of Engraving and Printing (BEP) announces the availability of the Draft Environmental Impact Statement (EIS) for the proposed construction and operation of a replacement Currency Production Facility (CPF) at the Beltsville Agricultural Research Center (BARC) in Prince George's County, Maryland. This is the Proposed Action.

DATES: Comments must be received by December 21, 2020 to be considered during preparation of the Final EIS.

ADDRESSES: Written comments may be *mailed to:* ATTN: Bureau of Engraving and Printing (BEP) Project EIS, U.S. Army Corps of Engineers (USACE), Baltimore District Planning Division, 2 Hopkins Plaza, 10th Floor, Baltimore, MD 21201, or *emailed to: BEP-EIS@usace.army.mil.* Comments may also be *submitted online through the project website* (*https://www.nab.usace.army.mil/Home/BEP-Replacement-Project/*) or *delivered verbally* during the public webinar, described below.

FOR FURTHER INFORMATION CONTACT: Please contact Mr. Harvey Johnson, USACE-Baltimore, Programs and Project Management Division by email at *BEP-EIS@usace.army.mil* or 410–977–6733. USACE has established a web page that contains information updates and background on this Draft EIS at *https://www.nab.usace.army.mil/Home/BEP-Replacement-Project/.*

SUPPLEMENTARY INFORMATION: In accordance with the National Environmental Policy Act (NEPA), the Draft EIS analyzes the potential environmental and socioeconomic impacts, and recommends related mitigation measures, associated with the Proposed Action. The Proposed Action would replace Treasury's existing and obsolete currency production functions located in downtown Washington, DC (DC Facility), and would provide Treasury with a modern, scalable, sufficiently sized production facility within the National Capital Region (NCR) that meets Treasury's needs.

The Proposed Action includes construction and operation of an up to 1 million square-foot CPF within the NCR. The Proposed Action would be implemented over an approximately nine-year period, from 2021 to 2029. This duration includes design, construction, equipment installation, acceptance testing to support full operations, and the sequenced transition of approximately 1,600 personnel from Treasury's DC Facility into the completed CPF. Currency manufacturing at the DC Facility would be phased out. The operational life of the Proposed Action is anticipated to be 50 years. Treasury would incorporate Environmental Protection Measures (EPMs), Regulatory Compliance Measures (RCMs), and Best Management Practices (BMPs) into the Proposed Action to proactively minimize

potential adverse environmental impacts and comply with applicable environmental regulatory requirements. Additional mitigation measures are recommended to further reduce adverse impacts.

A Draft Finding of No Practicable Alternative (FONPA) addressing potential impacts on wetlands is included in the Draft EIS for comment.

The BEP's mission includes manufacturing U.S. currency notes; research, development, testing, and evaluation of counterfeit deterrents; and development of production automation technologies. Treasury currently operates two production facilities for this purpose: The DC Facility and a facility in Fort Worth, Texas. The DC Facility has been in operation for more than 100 years and is neither able to support modern currency production nor Treasury's (and specifically the BEP's) current and future mission.

The condition, configuration, and location of the DC Facility severely limit Treasury's ability to modernize the DC Facility through renovation. Within the DC Facility, manufacturing processes are inefficient and increase staff safety risks; the location of the DC Facility does not allow Treasury to comply with modern physical security standards.

Over the past 20 years, Treasury has considered several scenarios to address the inadequacy of its current facilities in the NCR, including renovation of the DC Facility and new construction within the NCR. Treasury concluded that construction of a new replacement CPF, as opposed to renovation of the DC Facility, was the most efficient and cost-effective option. As such, Treasury proposes to construct and operate a new CPF on a minimum 100-acre parcel of federally owned, available land within the NCR to provide Treasury with a modern production facility, resulting in more efficient, streamlined currency production, and allowing Treasury to maintain its presence within the NCR.

The Draft EIS analyzes the potential environmental and socioeconomic impacts associated with the Proposed Action, including cumulative effects. Minimization of adverse effects through avoidance and environmentally sensitive design would be used to avoid impacts to sensitive resources to the maximum extent practicable. Where these efforts are not sufficient to avoid adverse effects, the Draft EIS recommends additional mitigation measures that Treasury may implement to further reduce identified adverse impacts.

In support of the EIS, Treasury, with assistance from USACE, is conducting site-specific studies in accordance with federal and state requirements, such as Sections 404/401 of the Clean Water Act (CWA) and Section 106 of the National Historic Preservation Act. The results of these studies will inform the design process and allow Treasury to minimize potential adverse impacts to the extent feasible.

As part of Treasury's planning process, it gathered data on potential sites in the NCR that could support a new CPF. Treasury evaluated each potential site against various screening criteria to identify reasonable alternatives. Treasury identified one reasonable Action Alternative (the Preferred Alternative) that would meet the purpose of and need for the Proposed Action. This Preferred Alternative is summarized below and analyzed in detail in the Draft EIS.

Preferred Alternative: BARC 200 Area

This alternative includes a 104.2-acre parcel of land located in BARC's Central Farm in the 200 Area building cluster. The parcel is located between Odell Road to the north and Powder Mill Road to the south; Poultry Road traverses the site. The parcel, generally consisting of grassland, cropland, scattered trees, and abandoned buildings, is available for redevelopment. Based on its alternatives screening process, Treasury determined that only this parcel met the purpose of and need for the Proposed Action, as well as the established site screening criteria. The Agriculture Improvement Act of 2018 specifically identified this parcel within the BARC 200 Area and included a Congressional authorization for the U.S. Department of Agriculture to transfer this parcel to Treasury for the purpose of constructing and operating the Proposed Action.

Treasury also carried forward the No Action Alternative for detailed analysis in the Draft EIS. While the No Action Alternative would not satisfy the purpose of or need for the Proposed Action, Treasury retained this Alternative to provide a comparative baseline against which to analyze the effects of the Preferred Alternative as required under the Council on Environmental Quality's regulations (40 Code of Federal Regulations 1502.14[c]).

Resource areas analyzed in the Draft EIS include: Land use; visual resources; air quality; noise; geology, topography, and soils; water resources; biological resources; cultural resources; traffic and transportation; utilities; socioeconomics and environmental justice (EJ); hazardous and toxic materials and waste; and human health and safety. Treasury dismissed air space and recreation from detailed study; through the public scoping process, Treasury determined the Proposed Action has no potential to cause significant adverse impacts to these resource areas.

Based on the Draft EIS analysis, potentially significant adverse impacts could occur to visual resources, water resources, cultural resources, traffic and transportation, and EJ communities (*i.e.,* from disproportionate adverse traffic impacts). Impacts to all other resource areas would be less-than-significant adverse, negligible, or beneficial. Recommended mitigation measures are presented in the Draft EIS to reduce potential adverse effects.

The Preferred Alternative for the Proposed Action would also adversely impact wetlands. Accordingly, Treasury prepared a Draft FONPA to comply with Executive Order 11990, *Protection of Wetlands.* As described in the Draft EIS, regulatory compliance measures (*e.g.,* permitting under Sections 404/401 of the CWA) would be implemented to minimize adverse impacts on wetlands.

Government agencies, Native American Tribes, and the public are invited to review and comment on the Draft EIS and Draft FONPA. The public comment period begins with the publication of this Notice of Availability in the **Federal Register** and will last for 45 days.

The Draft EIS and related materials are available on the project website at *https://www.nab.usace.army.mil/home/bep-replacement-project.* If you cannot access the Draft EIS materials online, please send a request for information *via email to: BEP-EIS@usace.army.mil;* or *via mail to:* ATTN: Bureau of Engraving and Printing (BEP) Project EIS, U.S. Army Corps of Engineers, Baltimore District Planning Division, 2 Hopkins Plaza, 10th Floor, Baltimore, MD 21201.

The public comment period also includes a virtual public meeting that will provide an opportunity for the public to learn about the Proposed Action (*i.e.,* Preferred Alternative), No Action Alternative, and environmental impact analysis. This meeting will be held online due to COVID–19 restrictions. The virtual public meeting includes two parts: (1) An online reading room and (2) a public webinar. The online reading room, available for the entire 45-day public comment period at *https://bep-eis.consultation.ai/,* contains public outreach and interpretive materials for the Draft EIS, as well as the Draft EIS itself. The public webinar will consist of a 2-hour online meeting wherein the BEP will give a brief presentation of the Draft EIS and solicit public comments; the specific details of this webinar, including the date, time, link, phone number, and password, will be announced on the

project website and in local media at least two weeks in advance of the webinar.

Following the public comment period, Treasury will consider all public comments and prepare and publish a Final EIS prior to making any decision regarding the Proposed Action. Comments must be received or postmarked by December 21, 2020 to be considered during preparation of the Final EIS.

David F. Eisner,

Assistant Secretary for Management, Department of the Treasury.

[FR Doc. 2020–24826 Filed 11–6–20; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 413

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 413

[CMS–1732–F]

RIN 0938–AU08

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2021. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, this rule updates requirements for the ESRD Quality Incentive Program (QIP).

DATES: These regulations are effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT: *ESRDPayment@cms.hhs.gov,* for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

Delia Houseal, (410) 786–2724, for issues related to the ESRD QIP.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose

This final rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), and the ESRD Quality Incentive Program (QIP).

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule updates and makes revisions to the ESRD PPS for CY 2021.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with acute kidney injury (AKI). Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule updates the AKI payment rate for CY 2021.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program fosters improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This final rule finalizes several updates for the payment year (PY) 2023. Although no new requirements were proposed for the PY 2024 ESRD QIP, this final rule includes policies continuing for PY 2024.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2021:* The final CY 2021 ESRD PPS base rate is $253.13. This amount reflects the application of the wage index budget-neutrality adjustment factor (.999485), the addition to the base rate of $9.93 to include calcimimetics, and a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.6 percent), equaling $253.13 (($239.33 × .999485) + $9.93) × 1.016 = $253.13).
- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2021, we are updating the wage index values based on the latest available data.

• *2018 Office of Management and Budget (OMB) delineations and 2-year transition policy:* We are updating the Office of Management and Budget (OMB) delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, beginning with the CY 2021 ESRD PPS wage index. In addition, we are finalizing the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. This transition will be phased in over 2 years, such that the reduction in an ESRD facility's wage index will be capped at 5 percent in CY 2021, and no cap will be applied to the reduction in the wage index for the second year, CY 2022.

• *Update to the outlier policy:* We are updating the outlier policy using the most current data, as well as updating the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2021 using CY 2019 claims data. Based on the use of the latest available data, the final FDL amount for pediatric beneficiaries will increase from $41.04 to $44.78, and the MAP amount will decrease from $32.32 to $30.88, as compared to CY 2020 values. For adult beneficiaries, the final FDL amount will increase from $48.33 to $122.49, and the MAP amount will increase from $35.78 to $50.92. The 1.0 percent target for outlier payments was not achieved in CY 2019. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent.

• *Inclusion of calcimimetics in the ESRD PPS base rate:* We are finalizing the methodology for modifying the ESRD PPS base rate to include calcimimetics in the ESRD PPS bundled payment. Using the final methodology based on the latest available data, we are adding $9.93 to the CY 2021 ESRD PPS base rate.

• *Changes to the eligibility criteria for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES):* For CY 2021, we are finalizing the proposed changes to the TPNIES eligibility criteria in light of the changes implemented in CY 2020 to provide a biannual coding cycle for code applications for new Healthcare Common Procedure Coding System (HCPCS) codes for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services. We are finalizing that for purposes of eligibility for the TPNIES, a complete HCPCS code application must be submitted by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website. In addition, a copy of the applicable Food and Drug Administration (FDA) marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. We are also finalizing the proposed definition of ''new'' for purposes of the TPNIES policy as within 3 years beginning on the date of the FDA marketing authorization.

• *Expansion of the TPNIES to include new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient:* We are expanding eligibility for the TPNIES to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. As with other renal dialysis equipment and supplies potentially eligible for the TPNIES, CMS will evaluate the application to determine whether the home dialysis machine represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries, and meets the other requirements under 42 CFR 413.236(b). We are finalizing the additional steps that the Medicare Administrative Contractors (MACs) must follow to establish the basis of payment of the TPNIES for these capital-related assets that are home dialysis machines when used in the home, including an offset to the pre-adjusted per treatment amount to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. We will pay 65 percent of the MAC-determined pre-adjusted per treatment amount reduced by an offset for 2-calendar years. We are finalizing that after the 2-year TPNIES period, the home dialysis machines will not become outlier services and that no change will be made to the ESRD PPS base rate.

• *Low-Volume Payment Adjustment (LVPA):* We are finalizing our proposal to hold harmless ESRD facilities that would otherwise qualify for the LVPA but for a temporary increase in dialysis treatments furnished in 2020 due to the Public Health Emergency (PHE) for the coronavirus disease 2019 (COVID–19) pandemic. For purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, we will only consider total dialysis treatments furnished for any 6 months of a facility's cost-reporting period ending in 2020; ESRD facilities will select those 6 months (consecutive or non-consecutive) during which treatments will be counted for purposes of the LVPA determination. We are finalizing that ESRD facilities will attest that their total dialysis treatments for those 6 months of their cost-reporting period ending in 2020 are less than 2,000 and that, although the total number of treatments furnished in the entire year otherwise exceeded the LVPA threshold, the excess treatments furnished were due to temporary patient shifting resulting from the COVID–19 PHE. MACs will annualize the total dialysis treatments for the total treatments reported in those 6 months by multiplying by 2. ESRD facilities will be expected to provide supporting documentation to the MACs upon request.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are updating the AKI payment rate for CY 2021. The final CY 2021 payment rate is $253.13, which is the same as the base rate finalized under the ESRD PPS for CY 2021.

3. ESRD QIP

We are finalizing our proposal to update the scoring methodology used to calculate the Ultrafiltration Rate reporting measure so that facilities are scored based on the number of eligible patient-months, instead of facility-months. We are also finalizing our proposal to reduce the number of records that facilities selected for National Health Safety Network (NHSN) validation are required to submit. This final rule also clarifies the timeline for facilities to make changes to their NHSN Bloodstream Infection (BSI) clinical measure and NHSN Dialysis Event reporting measure data for purposes of the ESRD QIP. This final rule also announces final performance standards and payment reductions that will apply for PY 2023.

This final rule describes several policies continuing for PY 2024, but does not include any new requirements beginning with the PY 2024 ESRD QIP.

C. Summary of Costs and Benefits

In section VI of this final rule, we set forth a detailed analysis of the impacts of the finalized changes for affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final CY 2021 ESRD PPS

The impact chart in section VI.B of this final rule displays the estimated change in payments to ESRD facilities in CY 2021 compared to estimated payments in CY 2020. The overall impact of the CY 2021 changes is projected to be a 2.0 percent increase in payments. Hospital-based ESRD facilities have an estimated 0.2 percent decrease in payments compared with freestanding facilities with an estimated 2.0 percent increase.

We estimate that the aggregate ESRD PPS expenditures will increase by approximately $250 million in CY 2021 compared to CY 2020. This reflects a $210 million increase from the payment rate update, a $50 million increase due to the updates to the outlier threshold amounts, and an $10 million decrease from the finalized addition to the ESRD PPS base rate to include calcimimetics and no longer provide the transitional drug add-on payment adjustment (TDAPA) for calcimimetics. As a result of the projected 2.0 percent overall payment increase, we estimate there will be an increase in beneficiary co-insurance payments of 2.0 percent in CY 2021, which translates to approximately $60 million.

These figures do not reflect increases or decreases in expenditures based on expanding the TPNIES to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. The fiscal impact of this cannot be determined because these new and innovative home dialysis machines are not yet identified and would vary in uniqueness and costs.

2. Impacts of the Final CY 2021 Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact chart in section VI.B of this final rule displays the estimated change in payments to ESRD facilities in CY 2021 compared to estimated payments in CY 2020. The overall impact of the final CY 2021 changes is projected to be a 5.7 percent increase in payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 5.8 percent increase in payments compared with freestanding ESRD facilities with an estimated 5.7 percent increase. The overall impact reflects the effects of the updated wage index, the finalized addition to the ESRD PPS base rate of $9.93 to include calcimimetics in the ESRD PPS bundled payment, and the payment rate update.

We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to AKI patients at the final CY 2021 ESRD PPS base rate will increase by $4 million in CY 2021 compared to CY 2020.

3. Impacts of the Final ESRD QIP

We estimate that the overall economic impact of the PY 2023 ESRD QIP would be approximately $224 million as a result of the policies we have previously finalized and the proposals we are finalizing in this final rule. The $224 million figure for PY 2023 includes costs associated with the collection of information requirements, which we estimate would be approximately $208 million, and $16 million in estimated payment reductions across all facilities. We note that the total overall economic impact and the collection of information requirements have been updated from the estimates in the proposed rule due to updated information about the total number of facilities participating in the ESRD QIP and the total number of patients. We also estimate that the overall economic impact of the PY 2024 ESRD QIP would be approximately $224 million as a result of the policies we have previously finalized. The $224 million figure for PY 2024 includes costs associated with the collection of information requirements, which we estimate would be approximately $208 million, and has been updated from the estimates in the proposed rule due to updated information about the total number of facilities participating in the ESRD QIP and the total number of patients.

II. Calendar Year (CY) 2021 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with CY 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, four comorbidity categories, and pediatric patient-level adjusters consisting of two age categories and two dialysis modalities (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second adjustment reflects differences in area wage levels developed from core based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

The ESRD PPS provides a training add-on for home and self-dialysis modalities (§ 413.235(c)) and an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (§ 413.237).

The ESRD PPS provides for a transitional drug add-on payment adjustment (TDAPA) for certain new renal dialysis drugs and biological products (§ 413.234(c)).

The ESRD PPS also provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for certain qualifying, new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

On November 8, 2019, we published a final rule in the **Federal Register** titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements,'' referred to as the ''CY 2020 ESRD PPS final rule''. In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy, for CY 2020. We also finalized revisions to the eligibility criteria for the TDAPA for certain new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category, modified the basis of payment for the TDAPA for calcimimetics, established a new policy to condition the TDAPA payment on our receipt of average sales price (ASP) data, established the TPNIES to support ESRD facilities in their uptake of certain new and innovative renal dialysis equipment and supplies, and discontinued the erythropoiesis-stimulating agent (ESA) monitoring policy under the ESRD PPS. For further detailed information regarding these updates, see 84 FR 60648.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Calendar Year (CY) 2021 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program'' (85 FR 42132 through 42208), referred to as the ''CY 2021 ESRD PPS proposed rule,'' was published in the **Federal Register** on July 13, 2020, with a comment period that ended on September 4, 2020. In that proposed rule, we proposed to make a number of annual updates for CY 2021, including updates to the ESRD PPS base rate, wage index, and outlier policy. We also proposed to modify the ESRD PPS base rate to incorporate calcimimetics, revise the eligibility criteria for the TPNIES, and expand the TPNIES to include capital-related assets that are home dialysis machines when used in the home by a single patient. We also proposed revisions to the low-volume payment adjustment (LVPA) regulations in response to the Public Health Emergency (PHE) for the coronavirus disease 2019 (COVID–19) pandemic. We received 114 public comments on our proposals, including comments from: ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses.

We also received many comments related to issues that we either did not discuss in the proposed rule or that we discussed for the purpose of background or context, but for which we did not propose changes. These include, for example, refinements to modeling payment and accounting for new and innovative items and services under the ESRD PPS, incentives for home dialysis, reporting furnished services on the ESRD claim, network fee, and issues related to the COVID–19 pandemic. While we are not addressing those comments in this final rule because they are either out of scope of the proposed rule or concern topics for which we did not propose changes, we thank the commenters for their input and will consider the recommendations in future rulemaking.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2021 ESRD PPS.

1. Inclusion of Calcimimetics Into the ESRD PPS Bundled Payment

a. Background on Oral-Only Renal Dialysis Drugs

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services,

and clause (iii) of such section states that these services include other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

We interpreted this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than ESAs and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biological products used for the treatment of ESRD and furnished under Title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B) of the Act, such drugs or biological products would fall under clause (iv) of such section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B) of the Act.

We finalized and promulgated the payment policies for oral-only renal dialysis service drugs and biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053), where we defined renal dialysis services at § 413.171 as including other drugs and biological products that are furnished to individuals for the treatment of ESRD and for which payment was made separately prior to January 1, 2011 under Title XVIII of the Act, including drugs and biological products with only an oral form. We further described oral-only drugs as those that have no injectable equivalent or other form of administration (75 FR 49038 through 49039). Although we included oral-only renal dialysis service drugs and biological products in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the PPS until January 1, 2014. In the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), we noted that the only oral-only drugs and biological products that we identified were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products, including allowing ESRD facilities additional time to make operational changes and logistical arrangements in order to furnish oral-only renal dialysis service drugs and biological products to their patients. Accordingly, we codified the delay in payment for oral-only renal dialysis service drugs and biological products at § 413.174(f)(6), and provided that payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form is incorporated into the PPS payment rates effective January 1, 2014. Since oral-only drugs are generally not a covered service under Medicare Part B, this delay of payment under the ESRD PPS also allowed the coverage under Medicare to continue under Part D.

On January 3, 2013, ATRA was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under § 413.176(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2016. Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS until January 1, 2016. We implemented this delay by revising the effective date at § 413.174(f)(6) from January 1, 2014 to January 1, 2016. In addition, we changed the date when oral-only renal dialysis service drugs and biological products would be eligible for outlier services under the outlier policy described in § 413.237(a)(1)(iv) from January 1, 2014 to January 1, 2016.

On April 1, 2014, PAMA was enacted. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA and precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2024. We implemented this delay in the CY 2015 ESRD PPS final rule (79 FR 66262) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2016 to January 1, 2024. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2016 to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available.

On December 19, 2014, ABLE was enacted. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, and precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2025. We implemented this delay in the CY 2016 ESRD PPS final rule (80 FR 69027 through 69028) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2024 to January 1, 2025. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025.

b. ESRD PPS Drug Designation Process and Calcimimetics

In addition to delaying implementation of the policy for oral-only renal dialysis service drugs and biological products under the ESRD PPS, discussed previously in this final rule, PAMA included section 217(c), which provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allows us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral-only, and a process to include new injectable and intravenous (IV) products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount to reflect the costs of furnishing that product.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by FDA. We defined an oral-only drug at § 413.234(a) to mean a drug or biological with no injectable equivalent or other form of administration other than an oral form.

Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). In the CY 2016 ESRD PPS final rule (80 FR 69024), we finalized that the drug designation process is dependent upon the ESRD PPS functional categories, consistent with our policy since the implementation of the PPS in 2011. We provided a detailed discussion on how we accounted for renal dialysis drugs and biological products in the ESRD PPS base rate

since its implementation on January 1, 2011 (80 FR 69013 through 69015). We explained that, in the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), in order to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at § 413.171) that would be included in the ESRD PPS base rate, we performed an extensive analysis of Medicare payments for Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. We stated in the CY 2011 ESRD PPS final rule that categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

In the CY 2016 ESRD PPS final rule, we also explained that, in CY 2011 ESRD PPS rulemaking, we grouped the injectable and IV drugs and biological products into ESRD PPS functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. In the CY 2016 ESRD PPS final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077).

We finalized a policy in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022) that, effective January 1, 2016, if a new injectable or IV product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. The ESRD bundled market basket updates the PPS base rate annually and accounts for price changes of the drugs and biological products reflected in the base rate.

We established in § 413.234(b)(2) that, if the new injectable or IV product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA described in § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to base the TDAPA on pricing methodologies under section 1847A of the Act and pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. During the time a new injectable or IV product is eligible for the TDAPA, it is not eligible as an outlier service. We established that, following payment of the TDAPA, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

We also established, in the CY 2016 ESRD PPS final rule (80 FR 69024 through 69027), an exception to the drug designation process for calcimimetics. We noted that in the CY 2011 ESRD PPS proposed and final rules (74 FR 49929 and 75 FR 49038, respectively), the only oral-only drugs and biological products we identified were phosphate binders and calcimimetics, which fall into the bone and mineral metabolism ESRD PPS functional category. We stated that we defined these oral-only drugs as renal dialysis services in our regulations at § 413.171 (75 FR 49044), delayed the Medicare Part B payment for these oral-only drugs until CY 2014 at § 413.174(f)(6), and continued to pay for them under Medicare Part D. We explained in the CY 2016 ESRD PPS final rule that, under § 413.234(b)(1), if injectable or IV forms of phosphate binders or calcimimetics are approved by FDA, these drugs would be considered reflected in the ESRD PPS bundled payment because these drugs are included in an existing functional category, so no additional payment would be available for inclusion of these drugs.

However, we recognized the uniqueness of these drugs and stated that we will not apply this process to injectable or IV forms of phosphate binders and calcimimetics when they are approved because payment for the oral forms of these drugs was delayed and dollars were never included in the ESRD PPS base rate to account for these drugs. Instead, we finalized a policy that once the injectable or IV phosphate binder or calcimimetic is FDA approved and has a Healthcare Common Procedure Coding System (HCPCS) code, we will issue a change request to pay for all forms of the phosphate binder or calcimimetic using the TDAPA based on the payment methodologies under section 1847A of the Act, which could include ASP + 6 percent, for a period of at least 2 years. We explained in the CY 2016 ESRD PPS final rule that this will allow us to collect data reflecting current utilization of both the oral and injectable or IV forms of the drugs, as well as payment patterns and beneficiary co-pays, before we add these drugs to the ESRD PPS bundled payment. We stated that during this period we will not pay outlier payments for these drugs. We further stated that at the end of the 2 or more years, we will adopt the methodology for including the phosphate binders and calcimimetics into the ESRD PPS bundled payment through notice-and-comment rulemaking.

In 2017, FDA approved an injectable calcimimetic. In accordance with the policy finalized in the CY 2016 ESRD PPS final rule, we issued a change request to implement payment under the ESRD PPS for both the oral and injectable forms of calcimimetics using the TDAPA. Change Request 10065, Transmittal 1889, issued August 4, 2017, replaced by Transmittal 1999, issued January 10, 2018, and implemented the TDAPA for calcimimetics effective January 1, 2018.

In CYs 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we made several revisions to the drug designation process regulations at § 413.234. In the CY 2019 ESRD PPS final rule, for example, we revised regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration, that is, new injectable, IV, oral, or other form or route of administration (83 FR 56932). In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories (83 FR 56942 through 56943). We also revised § 413.234(c) to reflect that we base the TDAPA on 100 percent of ASP (ASP + 0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP + 6). We explained that the 6 percent add-on to

ASP has been used to cover administrative and overhead costs, however, the ESRD PPS base rate includes dollars for administrative complexities and overhead costs for drugs and biological products, so we believe ASP + 0 is a reasonable basis for the TDAPA under the ESRD PPS (83 FR 56943 through 56944). For circumstances when ASP data is not available, we finalized that the TDAPA is based on wholesale acquisition cost (WAC) + 0 and, when WAC is not available, the TDAPA is based on the drug manufacturer's invoice (83 FR 56948). We also finalized a revision to § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics would continue to be based on the pricing methodologies available under section 1847A of the Act, which includes ASP + 6 (83 FR 56948). These provisions all had an effective date of January 1, 2020.

In the CY 2020 ESRD PPS final rule, we made several additional revisions to the ESRD PPS drug designation process regulations at § 413.234. For example, we revised § 413.234(b) and added paragraph (e) to codify certain eligibility criteria changes for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. That is, we excluded certain drugs from being eligible for the TDAPA, effective January 1, 2020 (84 FR 60672). Specifically, as detailed in the CY 2020 ESRD PPS final rule (85 FR 60565 through 60673), we excluded generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and drugs for which the new drug application (NDA) is classified by FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ''parent NDA'' is a Type 3, 5, 7 or 8—from being eligible for the TDAPA. We also established at § 413.234(c) a policy to condition application of the TDAPA on our receipt of ASP data (84 FR 60681).

In the CY 2020 ESRD PPS final rule (84 FR 60673), we also discussed the duration of payment of the TDAPA for calcimimetics and changed the basis of the TDAPA for such products. We stated that in accordance with our policy for calcimimetics under the drug designation process, we would pay for calcimimetics using the TDAPA for a minimum of 2 years until sufficient claims data for rate setting analysis is available for these products. We noted that at the time of the CY 2020 ESRD PPS proposed rule we were still in the process of collecting utilization claims data for both the oral and injectable form of calcimimetics. Therefore, in the CY 2020 ESRD PPS proposed rule, we stated that we would continue to pay for calcimimetics using the TDAPA in CY 2020 (84 FR 38347).

However, we also noted in the CY 2020 ESRD PPS proposed rule that we had provided the TDAPA for calcimimetics at ASP + 6 percent for 2-full years (that is, January 1, 2018 through December 31, 2019), and we believed that was sufficient time for ESRD facilities to address any administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics. We noted that it was clear that ESRD facilities were furnishing calcimimetics because payment for them using the TDAPA had increased Medicare expenditures by $1.2 billion in CY 2018 (84 FR 60673). We explained that one of the rationales for the 6 percent add-on to ASP was to cover administrative and overhead costs, however, the ESRD PPS base rate has dollars included for administrative complexities and overhead costs for drugs and biological products. Therefore, in the CY 2020 ESRD PPS final rule, we finalized a revision to § 413.234(c) to reflect that the basis of payment for the TDAPA for calcimimetics, beginning in CY 2020, would be 100 percent of ASP (84 FR 60676). We explained this policy change provided a balance between supporting ESRD facilities in their uptake of these products and limiting the financial burden that increased payments place on beneficiaries and Medicare expenditures. We also noted that this policy is consistent with the policy finalized for all other new renal dialysis drugs and biological products in the CY 2019 ESRD PPS final rule (83 FR 56948).

c. Methodology for Modifying the ESRD PPS Base Rate to Account for Calcimimetics in the ESRD PPS Bundled Payment

As we discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42138), under § 413.234(d), calcimimetics were no longer considered to be an oral-only drug once FDA approved an injectable calcimimetic in 2017. We explained that we have paid for calcimimetics under the ESRD PPS using the TDAPA since January 1, 2018. We stated in the CY 2016 ESRD PPS final rule that for calcimimetics—for which there is an ESRD PPS functional category, but no money in the base rate—we would utilize the TDAPA to collect utilization data before adding this drug to the ESRD PPS base rate. This would allow us to collect data reflecting current utilization of both the oral and injectable or IV forms of the drug, as well as payment patterns and beneficiary co-pays. The collection of this data for 2 or more years would allow us, with sufficient data, to incorporate these drugs into the ESRD PPS bundled payment through notice-and-comment rulemaking.

As we stated in the proposed rule, we believe we have collected sufficient claims data for a rate setting analysis for calcimimetics. Specifically, we have collected robust claims data for 2 full years and analyzed the utilization of every generic and brand name oral calcimimetic, along with the utilization of the injectable calcimimetic. We also monitored the ASP data for the calcimimetics coinciding with the specific utilization periods. Our overall analysis of ESRD claims data for CYs 2018 and 2019 indicated an increase in the utilization of the oral generic calcimimetic drugs and a steep decline in the utilization of brand-name oral calcimimetic. Weighting the ASP price data based on the utilization data resulted in an overall lower ASP because the generic calcimimetic drugs are less expensive than the brand calcimimetics. Since beneficiaries have a 20 percent co-pay under the ESRD PPS, a decrease in the payment for calcimimetics results in a decrease in the beneficiary co-pay.

Therefore, as we stated in the CY 2021 ESRD PPS proposed rule (85 FR 42138), we believed that we were at the step of the ESRD PPS drug designation process where we should propose to adopt the methodology for modifying the ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment, which we did in the CY 2021 ESRD PPS proposed rule. In this final rule, we are adding a per treatment amount to the ESRD PPS base rate to include the calcimimetics in the ESRD PPS bundled payment amount.

In developing the methodology for including calcimimetics into the ESRD PPS base rate, we considered the methodology that we used when we included Part B drugs and biological products in the ESRD PPS base rate as part of our implementation of the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49074 through 49079), we discussed how we established which renal dialysis drugs and biological products would be reflected in the ESRD PPS base rate. We used the utilization of those drugs and biological products from Medicare claims data and applied ASP + 6 percent to establish the price for each drug. Then we inflated each drug's price to 2011 using the Producer Price Index (PPI) for prescription drugs.

In addition, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49064), we established a dialysis treatment as the unit of payment. Consistent with the approach we used initially to include drugs and biological products into the ESRD PPS base rate and the ESRD PPS unit of payment, we proposed a similar methodology to calculate a one-time modification to the ESRD PPS base rate on a per-treatment basis to account for calcimimetics. We stated that the methodology is similar to the CY 2011 approach because we would determine utilization of the drug, in this case, calcimimetics, along with the payment amounts associated with each oral and injectable form based on the ASP + 0 instead of ASP + 6, as discussed in the CY 2020 ESRD PPS final rule.

The following sections discuss each element of our proposed methodology in detail. As an overview, we proposed to calculate a per-treatment amount for calcimimetics that would be added to the ESRD PPS base rate. We proposed to apply the value from the most recent calendar quarter ASP calculations at 100 percent of ASP (that is, ASP + 0) available to the public for calcimimetics to the utilization data for calcimimetics from CYs 2018 and 2019 Medicare ESRD claims data to provide the calcimimetic expenditure amount. We proposed to divide the calcimimetic expenditure amount by the total number of hemodialysis (HD)-equivalent dialysis treatments paid in CYs 2018 and 2019 under the ESRD PPS. We proposed to reduce this average per treatment amount by 1 percent to account for the outlier policy, since calcimimetics would be ESRD outlier services eligible for outlier payments beginning January 1, 2021. We proposed to add the resulting amount to the ESRD PPS base rate. We noted that this amount would be permanently included in the ESRD PPS base rate and be subject to the annual ESRD PPS payment updates (that is, the productivity-adjusted market basket increase and wage index budget neutrality adjustment factor). Under the proposal, CMS would stop paying for these drugs using the TDAPA for dates of service on or after January 1, 2021.

In the CY 2021 ESRD PPS proposed rule (85 FR 42141), we proposed to revise our drug designation regulation at § 413.234, by adding paragraph (f), to describe the methodology for modifying the ESRD PPS base rate to account for the costs of calcimimetics, including the data sources and the steps we would take to calculate a per treatment amount. We proposed, for dates of service on or after January 1, 2021, calcimimetics would no longer be paid for under the ESRD PPS using the TDAPA (§ 413.234(c)) and would be paid for through the ESRD PPS base rate and eligible for outlier payments as ESRD outlier services under § 413.237.

We noted that the proposed methodology would only modify the ESRD PPS base rate for calcimimetic drugs. As stated in the CY 2016 ESRD PPS final rule (80 FR 69022), the TDAPA would be paid for a minimum of 2 years, during which time we would collect and analyze utilization data. At the end of that time, the drug would be included within its new functional category and the base rate would potentially be modified to account for the cost of the drug, depending upon what the utilization data show. Accordingly, we explained, our policy is to propose and adopt this methodology when including any future eligible new renal dialysis drugs and biological products into the ESRD PPS base rate through notice-and-comment rulemaking.

(1) Determining Utilization of Calcimimetics

For use in the proposed calculation, we analyzed the utilization of both the oral and injectable forms of calcimimetics reported on the ESRD facility claims for CYs 2018 and 2019. ESRD facilities report this information to CMS on Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X. The oral calcimimetic is reported as HCPCS J0604 (Cinacalcet, oral, 1 mg, (for ESRD on dialysis)) and the injectable calcimimetic is reported as HCPCS J0606 (Injection, etelcalcetide, 0.1 mg), that is, one unit of J0604 is 1 mg, and one unit of J0606 is 0.1 mg. For purposes of this rate setting analysis, we considered utilization of calcimimetics as the units of the product furnished to an ESRD beneficiary.

For the CY 2018 utilization data for calcimimetics, we proposed to use the latest available claims data based on the CY 2018 ESRD facility claims updated through June 30, 2019 (that is, claims with dates of service from January 1 through December 31, 2018, that were received, processed, paid, and passed to the National Claims History (NCH) File as of June 30, 2019) to calculate 2018 utilization. Claims that are received, processed, paid, and passed to the NCH file are considered to be ''complete'' because they have been adjudicated.

For the CY 2019 utilization data for calcimimetics, we proposed to use the latest available claims data based on the CY 2019 ESRD facility claims updated through January 31, 2020 (that is, claims with dates of service from January 1 through December 31, 2019, that were received, processed, paid, and passed to the NCH File as of January 31, 2020).

In the CY 2021 ESRD PPS proposed rule (85 FR 42139), we stated that for the final rule, the latest available CY 2019 ESRD facility claims are those updated through June 30, 2020 (that is, claims with dates of service from January 1 through December 31, 2019, that were received, processed, paid, and passed to the NCH File as of June 30, 2020).

We explained that while we have continued to pay the TDAPA for calcimimetics for dates of service in CY 2020, we did not propose to use utilization data from this period because practice patterns in CY 2020 have been altered due to the COVID–19 pandemic and the resulting impact on data was unknown at that time. However, we noted that our policy to continue paying for calcimimetics using the TDAPA in CY 2020 allowed us to analyze 2 full years of adjudicated Medicare claims since CY 2019 claims include those claims from January 1, 2019 through December 31, 2019.

We solicited comments on the proposed use of CYs 2018 and 2019 claims data to determine the utilization of calcimimetics for purposes of calculating the proposed addition to the ESRD PPS base rate to account for calcimimetics at proposed § 413.234(f). We stated that we believed using claims data from CYs 2018 and 2019 is appropriate because those years provide us with not only the most complete data set, but also the most accurate data set reflecting paid claims. We also solicited comments as to whether we should instead use a single year (CY 2018 or CY 2019) rather than both CYs 2018 and 2019 in our methodology.

(2) Pricing of Calcimimetics—Methodology

We proposed to set the price for calcimimetics using values from the most recent calendar quarter of ASP calculations available to the public, at 100 percent of ASP (ASP + 0). As we explained in the CY 2021 ESRD PPS proposed rule, the ASP-based value is a CMS-derived weighted average of all of the National Drug Code (NDC) sales prices submitted by drug manufacturers and assigned by CMS to the two existing HCPCS codes for calcimimetics. For each billing code, CMS calculates a weighted average sales price using data submitted by manufacturers, which includes the following: ASP data at the 11-digit NDC level, the number of units of the 11-digit NDC sold and the ASP for those units. Next, the number of billing units in an NDC is determined by the

amount of drug in the package. CMS uses the following weighting methodology to determine the payment limit: (1) Sums the product of the manufacturer's ASP and the number of units of the 11-digit NDC sold for each NDC assigned to the billing and payment code; (2) divides this total by the sum of the product of the number of units of the 11-digit NDC sold and the number of billing units in that NDC for each NDC assigned to the billing and payment code, and (3) weights the ASP for an NDC by the number of billing units sold for that NDC. This calculation methodology is discussed in the CY 2009 Physician Fee Schedule (PFS) final rule (73 FR 69752). The general methodology for determining ASP-based payments for the PFS is authorized in section 1847A of the Act.

We noted that ASP-based payment limits published in the quarterly ASP Drug Pricing files include a 6 percent add-on as required in section 1847A of the Act; however, consistent with the TDAPA basis of payment for CY 2020, we proposed to use 100 percent of the weighted ASP value, in other words, ASP + 0. In the CY 2020 ESRD PPS final rule, we noted that the ESRD PPS accounts for storage and administration costs and that ESRD facilities do not have acquisition price variation issues when compared to physicians. We explained that we believed ASP + 0 is reasonable for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We also explained that we believed ASP + 0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that do not fall within the existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products (83 FR 56946).

As stated in the CY 2021 ESRD PPS proposed rule, we believe using a value based on the most recent calendar quarter ASP calculations available to the public for both oral and injectable versions of the calcimimetics provides an accurate representation of the price of calcimimetics for ESRD facilities because it uses manufacturer sales information that includes discounts (that is, rebates, volume discounts, prompt payment, cash payment specified in section 1847A of the Act). Every calendar quarter, CMS publishes ASP-based payment limits for certain Part B drugs and biological products that are used for payment of such Part B covered drugs and biological products for a specific quarter. The amount that we proposed to use for the base rate modifications associated with the oral and injectable versions of the calcimimetics is based on the most recent information on average sales prices net of discounts specified in section 1847A submitted by the manufacturers of each of the drugs.

For the CY 2021 ESRD PPS proposed rule, values from the most recent calendar quarter of ASP calculations available to the public was the second quarter of 2020,[1] and as a result of the two-quarter data lag this reflects manufacturer sales data submitted into CMS for the fourth quarter of 2019. We stated that for the CY 2021 ESRD PPS final rule, the most recent calendar quarter of ASP calculations available to the public would be the fourth quarter of 2020, which reflects manufacturer sales data submitted into CMS for the second quarter of 2020, and we would use that value for purposes of our final calculation.

We proposed to update these prices by the proposed CY 2021 ESRD PPS base rate update to reflect the estimated costs in CY 2021. That is, we would first add the calculated per treatment payment amount to the ESRD PPS base rate to include calcimimetics, and then we would apply the annual payment rate update. The proposed calculation for the addition to the ESRD PPS base rate is discussed in the following section.

Therefore, we proposed to add § 413.234(f) to specify that CMS would use 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for the oral and injectable calcimimetic to calculate a price for each form of the drug. We solicited comments on the proposed use of the values from the most recent calendar quarter ASP + 0 calculations available to the public for calcimimetics for setting the price and the proposed language at § 413.234(f).

(3) Calculation of the Addition to the ESRD PPS Base Rate To Include Calcimimetics

To calculate the proposed amount for calcimimetics that would be added to the ESRD PPS base rate, we applied the values from the most recent calendar quarter 2020 ASP + 0 calculations available to the public for calcimimetics to CYs 2018 and 2019 calcimimetic utilization data to calculate the calcimimetic expenditure amount for both years. As stated in the proposed rule and section II.B.1.c.(1) of this final rule, one unit of J0604 (oral calcimimetic, cinacalcet) is 1 mg and one unit of J0606 (injectable calcimimetic etelcalcetide) is 0.1 mg. That is, we determined that 1,824,370,957 total units (mg) of oral calcimimetics were used in CYs 2018 and 2019. With regard to injectable calcimimetics, we determined that 306,714,207 total units (0.1 mg) were used in CYs 2018 and 2019. This use indicates that 33.9 percent of ESRD beneficiaries received calcimimetics in CYs 2018 and 2019. For the CY 2021 ESRD PPS proposed rule, we used the values from the most recent calendar quarter ASP + 0 calculations available to the public, which at the time of rulemaking was the second quarter of 2020. This information can be found on the ESRD Payment website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.* We used $0.231 per mg for the oral calcimimetic and $2.20 per 0.1 mg for the injectable calcimimetic. The prices per unit correspond to 1 mg and 0.1 mg for cinacalcet and etelcalcetide respectively. (We noted that, for the CY 2021 ESRD PPS final rule, we would update the ASP + 0 based value on the most recent calendar quarter calculations available to the public.) Multiplying the utilization of the oral and injectable calcimimetics by their respective ASP and then adding the expenditure amount for both forms of calcimimetics together would be the total 2-year (CYs 2018 and 2019) calculated calcimimetic expenditure amount. That is, for the CY 2021 ESRD PPS proposed rule, we calculated the total calcimimetic expenditure amount of $1,096,200,947. The total number of paid HD-equivalent dialysis treatments furnished to Medicare ESRD beneficiaries in CYs 2018 and 2019 was 90,014,098. This total number of paid treatments reflects all paid dialysis treatments regardless of whether a calcimimetic was furnished. Dividing the calcimimetic expenditure amount by the total number of paid HD-equivalent dialysis treatments provides an average per treatment payment amount of $12.18.

We then reduced this amount by 1 percent to account for the outlier policy under § 413.237 to get a total of $12.06 ($12.18 × .99 = $12.06). Under our proposal, we would apply this 1 percent reduction before increasing the base rate to account for outlier payments that would be paid beginning January 1, 2021 for calcimimetics since they would become ESRD outlier services eligible

[1] *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files,* April 2020 ASP Pricing File.

for outlier payments under § 413.237. As we discussed in the proposed rule and section II.B.1.c of this final rule, in developing the proposed methodology for including calcimimetics in the ESRD PPS base rate, we considered the methodology applied when we developed the ESRD PPS base rate. In the CY 2011 ESRD PPS final rule (75 FR 49074 through 49075), we explained the budget neutrality adjustments applied to the unadjusted ESRD PPS base rate to account for statutorily mandated reductions. Because calcimimetics would become ESRD outlier services beginning January 1, 2021, we focused on the outlier adjustment. That is, in CY 2011 we applied a 1 percent reduction to the unadjusted ESRD PPS base rate to account for outlier payments. In order for the application of the 1 percent outlier to be maintained, we stated that we believe the 1 percent must be excluded from the addition to the ESRD PPS base rate for calcimimetics.

Then, to determine the estimated costs in CY 2021 we proposed to inflate the average per treatment payment amount for calcimimetics ($12.06) to 2021 using the CY 2021 ESRD PPS base rate update. As discussed in section II.B.4.d of the CY 2021 ESRD PPS proposed rule (85 FR 42164), the proposed CY 2021 ESRD PPS base rate was $255.59. This amount reflected a proposed CY 2021 wage index budget-neutrality adjustment factor of .998652, a proposed base rate addition of $12.06 to include calcimimetics, and the proposed CY 2021 ESRD PPS payment rate update of 1.8 percent. We stated that using the annual payment rate update effectively updates the prices set for calcimimetics from CY 2020 to CY 2021 because this is consistent with how the other components of the base rate are updated for inflation each year, which includes drugs. We noted, that the inflation factor used for drugs and biological products for the ESRD bundled market basket is the Producer Price Index as discussed in the CY 2019 ESRD PPS final rule (83 FR 56958 through 56959).

Therefore, we proposed to add § 413.234(f) to specify that CMS would multiply the utilization of the oral and injectable calcimimetics by their respective prices and add the expenditure amount for both forms together to calculate the total calcimimetic expenditure amount. Then, CMS would divide the total calcimimetic expenditure amount by the total number of paid HD-equivalent dialysis treatments in CYs 2018 and 2019, to calculate the average per-treatment payment amount. CMS would reduce the average per-treatment payment amount by 1 percent to account for the outlier policy under § 413.237 in order to determine the amount added to the ESRD PPS base rate.

We stated in the CY 2021 ESRD PPS proposed rule that, in keeping with the principles of a PPS, which include motivating healthcare providers to structure cost-effective, efficient patient care that avoids unnecessary services, thereby reining in costs, we believe the cost of the calcimimetics should be spread across all the dialysis treatments, rather than be directed only to the patients receiving the calcimimetics.

We solicited comments on the proposed revisions to § 413.234 to add paragraph (f) to § 413.234 to establish the methodology for modifying the ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment.

As an alternative methodology, we considered dividing the total Medicare expenditures for all calcimimetics in CYs 2018 and 2019 (approximately $2.3 billion) by the total number of paid HD-equivalent dialysis treatments furnished during that same time period. However, we noted that this approach would not factor in the impact of oral generic calcimimetics, which entered the market from late December 2018 through early January 2019. For example, under the proposed methodology, the ASP calculations incorporate the more recent pricing of the oral generic calcimimetics into the weighting which has resulted in a significant decline in the ASP-based value. In addition, this alternative methodology would not reflect our current policy to base the TDAPA on ASP + 0, since in CYs 2018 and 2019 we paid for calcimimetics using the TDAPA at ASP + 6. We stated that we believe it is more appropriate for the ESRD PPS base rate to reflect the values from the most recent calendar quarter of ASP calculations available since that aligns with how ESRD facilities would be purchasing and furnishing the oral calcimimetics rather than using expenditure data from previous periods. We further stated that we believe that ESRD facilities would want to support CMS's goal of lower drug and biological products prices for its beneficiaries. In addition, we noted, this alternative methodology would have a more significant impact on beneficiary cost sharing in terms of a higher 20 percent co-pay than the methodology in the proposed rule. We solicited comment on this alternative methodology, which would entail dividing the total Medicare expenditures (that is, actual spend) for all calcimimetics in CYs 2018 and 2019 by the total number of paid HD-equivalent dialysis treatments furnished during that same time period.

The comments and our responses to the comments on our proposed methodology for including calcimimetics in the ESRD PPS base rate are set forth below.

Comment: The majority of commenters recommended that CMS trim the analysis data set to exclude data that is not representative of steady utilization trends. The commenters were supportive of CMS collecting 2 full years of data for rate-setting purposes, but disagreed with the methodology to incorporate the full data set into the analysis. Specifically, the commenters recommended CMS remove CY 2018 claims utilization from the analysis because it includes early utilization data from CY 2018, the first year that CMS began paying for calcimimetics under the ESRD PPS using the TDAPA. Commenters described various changes occurring with regard to calcimimetics, including changes in prescriber behavior, facility operational systems, and the use of oral and IV calcimimetic products. The commenters asserted that the following factors make utilization data from 2018 inaccurate because the data fails to account for: (1) Slow adoption of the intravenous form of calcimimetics due to the change in payment for the drugs under Part D to Part B; (2) the time it takes for ESRD facilities to adopt new treatment methods; and (3) a recent steady increase in clinical utilization.

The commenters stated that the first quarter of 2018 is not an accurate depiction of utilization because many beneficiaries had a supply of oral calcimimetics that was paid under the Part D benefit from 2017, being used at the start of 2018, which reduced utilization under Part B. The commenters also stated that moving the payment from Medicare Part D to Part B disrupted business and billing practices for ESRD facilities. The commenters maintained that small and independent ESRD facilities had a difficult time incorporating calcimimetics into clinical practice compared to larger and hospital-based facilities. The commenters explained that ESRD facilities usually need a longer time to institute system modifications and adjust business practices when new treatment methods become available.

The commenters stated that in the beginning of 2018 the new intravenous form of calcimimetics was approved for treatment, and clinical adoption has been gradual because it was a new form of treatment, which is evidenced by

very low utilization in the early part of CY 2018 followed by steady growth throughout the year, as shown in the Part B claims data. The commenters stated that, while use of the intravenous drug increased each quarter in 2018, the pace of that increase flattened out during CY 2019.

The commenters stated that due to these challenges and shifts in utilization, they believed that claims data from CY 2018 reflected lower units of calcimimetics being reported. A few commenters who disagreed with including CY 2018 claims in the analysis, suggested CMS trim the first and second quarter of 2018 utilization data from the data set; however, another subset of commenters recommended CMS remove the entire year of 2018 data and use CY 2019 data only, since their analysis shows that year of data to be stable. The majority of the commenters who disagreed with including the CY 2018 data recommended that CMS use the most recent 12 months for which complete claims data are available for rate-setting purposes. In addition, the commenters asserted that using the most recent utilization data would align with the proposed approach to use the most recent ASP.

MedPAC supported increasing the ESRD PPS base rate to include the costs of calcimimetics in the ESRD PPS bundled payment. However, MedPAC recommended refinements to CMS's proposed methodology to use units reported on claims from both CYs 2018 and 2019 to determine utilization for calcimimetics. MedPAC recommended that CMS use only the single year of claims data that would result in the lowest add-on payment amount for these products. MedPAC stated that this approach would be consistent with the methodology used to establish the ESRD PPS base rate beginning January 1, 2011, as required under MIPPA, which provided that the estimated amount of total payments under the ESRD PPS for 2011 must be made based on the lowest per patient utilization data from 2007, 2008, or 2009. (Based on CMS's analysis in the CY 2011 ESRD PPS final rule, claims data from CY 2007 reflected the lowest utilization of ESRD services.) MedPAC noted the increase of utilization in ESAs prior to the CY 2011 ESRD PPS final rule and recommended that our methodology to include calcimimetics in the base rate be consistent with the lowest per patient utilization methodology. Therefore, MedPAC recommended that CMS use the year that would result in the lowest average payment amount per treatment for calcimimetics.

Response: We appreciate the feedback on our proposal and the viewpoints expressed by the commenters. Based on the recommendations we received to use a single year or the most recent 12 months of claims data, we re-examined the most recently available data. First, an approach that uses the most recent 12 months of claims data would result in a base rate increase that is larger than when both 2018 and 2019 data are used. Second, using the most recent 12 months of claims data would not sufficiently capture the developments with calcimimetics that took place at the end of 2018. For these reasons, we believe this is not the better approach.

Next, using only 2019 claims data would diminish the impact of the entry of oral generic calcimimetics into the market in mid-2018. In examining the 2 full years of data, we see a continued increase in the utilization of the oral generic calcimimetic drugs, a steep decline in the brand-name oral calcimimetic, and a slow increase in the brand-name injectable version. Using only CY 2019 claims data would also result in a base rate increase that is larger than when both CYs 2018 and 2019 data are used. We recognize the 2018 claims data may have demonstrated low uptake for the injectable calcimimetic, but it also may reflect that the significant upswings in utilization of the injectable calcimimetic in 2019 were from ESRD facilities anticipating CMS ending the TDAPA for calcimimetics beginning January 2020. As MedPAC noted, when the ESRD PPS was implemented in 2011, there had been a pattern of ESA overutilization before the ESRD PPS bundled payment was implemented and a decline in utilization of ESAs post-implementation of the ESRD PPS that required a rebasing of the amount included in the ESRD PPS bundled payment for ESAs. We believe it is appropriate to consider both the slow uptake of the injectable calcimimetic and the ramping up of utilization of generic oral calcimimetics, following the loss of the exclusivity of the brand name product in addition to the anticipation of the TDAPA ending in 2019. If we used only CY 2019 data, we believe that we would be overestimating the use of calcimimetics in the ESRD PPS bundled payment. For these reasons, we also believe using only 2019 claims data for rate setting is not the better approach.

Lastly, we examined an approach that would take into account some commenters' request for the lowest add-on payment amount, other commenters' request to focus on more recent data, and CMS's goal to use a robust data set that accounts for the different types of medication and innovation. For this approach, we examined 18 months of claims data starting with the third quarter of 2018 through the fourth quarter of 2019. In reviewing the 18 months of data, we continue to capture the increase in the utilization of the oral generic calcimimetic drugs and the decline in the brand-name oral calcimimetic, which, as we noted above, was apparent to us when we examined the full 2 years of data. Using the 18 months of data from the third quarter of 2018 through the fourth quarter of 2019 would result in a base rate increase that is larger than when both CYs 2018 and 2019 data are used, but smaller than when only CY 2019 is used. We believe the data set should reflect both the slow uptake of the injectable calcimimetic and the ramping up of utilization of generic oral calcimimetics. We also believe that the commenters are reasonable in wanting to incorporate more recent data in the utilization, and view the use of 18 months of data as a mid-point between the proposal and what commenters suggested is appropriate. Accordingly, we have concluded that using 18 months of claims data is the most appropriate approach. We also agree with commenters that there have been shifts in the utilization of calcimimetics. We believe that the shifts in utilization reveal a rapidly changing market. We plan to revisit the calcimimetic Medicare expenditures in the future, such as when a generic injectable comes on the market.

We believe using 18 months of claims data provides us with the most accurate data set reflecting paid claims for generic and brand-name oral calcimimetic, along with the injectable calcimimetic. Therefore, for this final rule, we used adjudicated claims from the third quarter of 2018 through the fourth quarter of 2019 in the final calculation of the modification to the base rate. For the CY 2018 utilization data for calcimimetics, we used the latest available claims data based on the third and fourth quarters of CY 2018 ESRD facility claims, updated through June 30, 2019 (that is, claims with dates of service from July 1 through December 31, 2018, that were received, processed, paid, and passed to the NCH file as of June 30, 2019). For CY 2019 utilization data, we used the latest available CY 2019 ESRD facility claims, updated through June 30, 2020 (that is, claims with dates of service from January 1 through December 31, 2019, that were received, processed, paid, and passed to the NCH file as of June 30, 2020).

Comment: MedPAC recommended that we set the price for calcimimetics

using values from the calendar quarter of ASP data that would result in the lowest total expenditures for these drugs, at ASP+0. MedPAC also stated that using the most recent calendar quarter of 2020 ASP data would best reflect the increasing use of oral generic calcimimetics, which entered the market in late December 2018, and how ESRD facilities are likely to purchase and furnish the oral calcimimetics in the future. MedPAC recommended this methodology because it is consistent with how CMS bases the price for calcimimetics under current regulations. MedPAC strongly supported pricing for calcimimetics under the proposed methodology at ASP+0.

The majority of the commenters recommended that CMS calculate the price using the most recent quarter ASP data available at ASP+6 because they believed this would more accurately reflect the cost ESRD facilities incur when purchasing and administering these drugs. Commenters stated that most small and independent providers experience less favorable acquisition costs for calcimimetics than other provider types, with costs that exceed 100 percent of ASP. The commenters stated that CMS's methodology should account for actual acquisition costs incurred by providers, especially small and independent providers with limited resources, and for these reasons, recommended that the methodology be refined to add the price for calcimimetics at ASP+6 rather than ASP+0.

Response: We appreciate the feedback we received from the commenters with regard to our proposal to base pricing for calcimimetics at ASP+0. We agree with MedPAC that ASP+0 is appropriate as the basis for calcimimetics. Although some commenters suggested that the base pricing for calcimimetics should be ASP + 6, we believe this would be a duplicative payment because the 6 percent accounts for storage and administration of drugs and drug products, along with routine administrative costs, and these costs are already included in the ESRD PPS base rate. We understand the concerns expressed by the commenters about ASP, and the difficulties that small ESRD facilities may encounter if they are unable to negotiate the lower drug prices attributed to volume, and inaccessibility to supply chain discounts; however, we do not think this overrides the concern about providing duplicative payment. As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56945), the intent of the TDAPA is to support ESRD facilities in the uptake of the drugs and biological products that are eligible for the add-on payment adjustment. In addition to the reasons discussed previously, and since our payment policy for the TDAPA is based on ASP+0, we believe basing the price for calcimimetics in the ESRD PPS base rate on ASP+0 is appropriate and consistent with our policy; therefore we are finalizing as proposed.

Comment: A few commenters recommended CMS create a methodology for a beneficiary-targeted add-on payment to the ESRD PPS base rate. The commenters recommended a targeted adjustment for the oral calcimimetic and a separate adjustment for the intravenous calcimimetic, given that only a subset of beneficiaries receive calcimimetics and the costs of calcimimetics would be targeted to only beneficiaries receiving the drug. MedPAC agreed with our proposal to spread the cost of calcimimetics across all dialysis treatments, rather than just for the treatments of beneficiaries receiving the drugs.

Response: The ESRD PPS is a payment system based on the ''average patient,'' which means it is based on the costs of the average patient. Currently, payment under the ESRD PPS is not targeted towards patients who utilize specific drugs, items, or services. Our proposed methodology would result in a flat increase to the base rate for all treatments and would not vary when facilities use more or less than the average amount. We believe the proposed methodology aligns with how other services are paid under the bundled payment system and reflects the average cost for furnishing renal dialysis services to patients. Therefore, we are finalizing this aspect of our proposal as proposed.

Comment: A few commenters disagreed with the proposed methodology to reduce the average per-treatment payment amount by 1 percent. The commenters stated that it would be harder for ESRD facilities to meet the eligibility requirements for outlier payments in CY 2021 and beyond.

Response: Beginning January 1, 2021, calcimimetics are eligible for outlier payments. In the CY 2011 ESRD PPS final rule, we applied a 1 percent reduction to the unadjusted ESRD PPS base rate to account for outlier payments. An ESRD facility that treats beneficiaries with unusually high resource requirements, as measured by their use of identified services beyond a specified threshold, is entitled to outlier payments. In order for the application of the 1 percent outlier to be maintained, we believe 1 percent must be excluded from the addition to the ESRD PPS base rate for calcimimetics. We continue to believe that a 1 percent outlier payment adjustment balances the need to pay for unusually costly resource-intensive cases, while also ensuring an adequate add-on to the base rate for beneficiaries who do not qualify for outlier payments. Therefore, we are finalizing this aspect of our proposal as proposed.

Comment: Some commenters stated that CMS should not use the alternative method discussed in the CY 2021 ESRD PPS proposed rule, under which total calcimimetic expenditures would be divided by the total number of HD-equivalent dialysis treatments in 2018 and 2019. The commenters stated that the alternative method expenditures for calcimimetics is based upon the previous policy of paying ASP+6 percent and does not reflect ASP+0. The commenters stated that the alternative method would likely result in a much higher increase to the base rate, which in turn would result in higher cost-sharing for beneficiaries. The commenters agreed that the alternative method does not factor in the impact of the oral generic calcimimetics, whereas the proposed methodology incorporates the recent pricing of oral generic calcimimetics into the weighting.

Response: We agree with the commenters' assessment of the alternative methodology, that it does not factor in the impact of oral generic calcimimetics and does not reflect ASP+0, and we are not adopting it in this final rule. We continue to believe that it is more appropriate for the ESRD PPS base rate to reflect the values from the most recent calendar quarter of ASP calculations available, since that aligns with how ESRD facilities would be purchasing and furnishing the oral calcimimetics, rather than using expenditure data from previous periods. Further, including the higher payment for oral calcimimetics that have lower priced generic equivalents is not in keeping with the agency's overall goals of lowering drug prices.

Comment: We received several comments that were beyond the scope of the proposed rule. Some commenters stated that CMS should apply the 3-year data collection policy to all TDAPA-eligible therapies in the future because it is critical for CMS to have 2-full calendar years of claims data (which requires 3 years of payment of the TDAPA to address data lags) to enable an appropriate understanding of actual product utilization in clinical care.

Response: Currently, the TDAPA payment is applicable for a minimum period of 2 years. For new drugs and biological products that are eligible for the TDAPA in the future and are not considered included in the ESRD PPS

base rate, CMS will continue to require that the TDAPA is paid until sufficient claims data for rate setting analysis is available, as required by the regulations. When a new renal dialysis drug or biological product is already included in a functional category, then the purpose of the TDAPA is to facilitate uptake of the new product into the business process of the ESRD facility. Although we would collect the data for purposes of analyzing utilization, we would not collect it for purposes of a potential modification to the base rate. Therefore we would not need 3 years of data for those drugs.

Comment: Some commenters stated concerns with the payment increase to the patient's out-of-pocket cost due to the proposed increase to the ESRD PPS bundled payment for calcimimetics, and recommended CMS keep the financial burden to the beneficiary population in consideration.

Response: We understand that beneficiary coinsurance is a concern. When evaluating the methodology for modifying the ESRD PPS base rate for calcimimetics, we were cognizant of the burden of beneficiary co-insurance and worked to strike a balance with beneficiary need for access at a reasonable price, and supporting a new therapy for a significant portion of the dialysis population. We believe the final policy for the inclusion of dollars in the base rate strikes the balance we are seeking.

Final Rule Action: After consideration of the comments we received, we are finalizing § 413.234 to add paragraph (f), which establishes the methodology for modifying the ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment, as proposed, with one modification. We are using claims data from the third quarter of CY 2018 through the fourth quarter of CY 2019, instead of CYs 2018 and 2019 claims data, to determine the utilization of calcimimetics for purposes of our methodology.

Specifically, to calculate the final amount for calcimimetics to be added to the ESRD PPS base rate beginning January 1, 2021, we applied the values from the most recent calendar quarter 2020 ASP + 0 calculations available to the public for calcimimetics to the utilization period of third quarter of 2018 through the fourth quarter of 2019 to calculate the calcimimetic expenditure amount for 18 months.

We determined that 1,350,414,515 total units (mg) of oral calcimimetics were used from Q3 2018 through Q4 2019. With regard to injectable calcimimetics, we determined that 280,998,916 total units (0.1 mg) were used from Q3 2018 through Q4 2019. We used the values from the most recent calendar quarter ASP + 0 calculations available to the public, which is the fourth quarter of 2020. We used $0.085 per mg for the oral calcimimetic and $2.023 per 0.1 mg for the injectable calcimimetic. The prices per unit correspond to 1 mg and 0.1 mg for cinacalcet and etelcalcetide, respectively. Multiplying the utilization of the oral and injectable calcimimetics by their respective ASP and then adding the expenditure amount for both forms of calcimimetics together results in the total 18-months (Q3 2018 through Q4 2019) calculated calcimimetic expenditure amount. That is, for this final rule, we calculated the total calcimimetic expenditure amount to be $683,246,041.

The total number of paid HD-equivalent dialysis treatments furnished to Medicare ESRD beneficiaries from the third quarter of CY 2018 through the fourth quarter of CY 2019 was 68,148,651. This total number of paid treatments reflects all paid dialysis treatments regardless of whether a calcimimetic was furnished. Dividing the calcimimetic expenditure amount by the total number of paid HD-equivalent dialysis treatments provides an average per treatment payment amount of $10.03. We then reduced this amount by 1 percent to account for the outlier policy under § 413.237 to get a total of $9.93 ($10.03 × .99 = $9.93). Due to the effect of generic calcimimetics in lowering the drug prices for calcimimetics, $9.93 is the final amount added to the CY 2021 ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment.

2. Changes to the TPNIES Eligibility Criteria

a. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established a transitional add-on payment adjustment for certain new and innovative renal dialysis equipment and supplies under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, in order to support ESRD facility use and beneficiary access to these new technologies. We established this payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the transitional add-on payment adjustment for new and innovative renal dialysis equipment and supplies, which we call the TPNIES.

We established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, CMS will provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) Has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, (4) has a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year, (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1) and related guidance, and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that CMS will use the following criteria to evaluate substantial clinical improvement (SCI) for purposes of the TPNIES under the ESRD PPS, based on the inpatient hospital prospective payment system (IPPS) SCI criteria in § 412.87(b)(1) and related guidance. Section 412.87(b)(1) includes the criteria used under the IPPS new technology add-on payment (NTAP) to determine whether a new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

The totality of the circumstances is considered when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

A determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or

• The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or

• The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: (1) A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; (5) an improvement in one or more activities of daily living; (6) an improved quality of life; or (7) a demonstrated greater medication adherence or compliance; or,

• The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Evidence from the following published or unpublished information sources from within the United States (U.S.) or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

The medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

The new renal dialysis equipment or supply may represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

We also established a process modeled after IPPS's process of determining if a new medical service or technology meets the SCI criteria specified in § 412.87(b)(1). Specifically, similar to the IPPS NTAP, we wanted to align our goals with the agency's efforts to transform the healthcare delivery system for the ESRD beneficiary through competition and innovation to provide patients with better value and results. As we discuss in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payments similar to the IPPS NTAP program and to provide innovators with standard criteria for both inpatient and outpatient settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we will announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. The TPNIES applications for CY 2021 were discussed in section II.C.2 of the CY 2021 ESRD PPS proposed rule as well as section II.C.2 of this final rule. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year, meaning the year in which the payment adjustment would take effect, and FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. We stated in the CY 2020 ESRD PPS final rule (80 FR 60690) that we would establish a workgroup of CMS medical and other staff to review the studies and papers submitted as part of the TPNIES application, the public comments we receive, and the FDA marketing authorization and HCPCS application information and assess the extent to which the product provides SCI over current technologies.

We established § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply. Section 413.236(d)(1) states that the TPNIES is paid for 2-calendar years. Section 413.236(d)(2) provides that, following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Under § 413.236(e)(1), the Medicare Administrative Contractors (MACs), on behalf of CMS, will establish prices for the new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in § 413.236(b) using verifiable information from the following sources of information, if available: (1) The invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

b. Changes to Eligibility for the TPNIES

Currently, in § 413.236(b)(2), one eligibility requirement for the TPNIES is that an equipment or supply must be new, meaning it is granted marketing authorization by FDA on or after January 1, 2020. In establishing this requirement, we tied what is considered new to January 1, 2020, the effective date of the TPNIES policy. We explained in the CY 2020 ESRD PPS final rule (84 FR 60685) that by including FDA marketing authorizations on or after January 1, 2020, we intended to support ESRD facility use and beneficiary access to the latest technological improvements to renal dialysis equipment and supplies. As we stated in the CY 2021 ESRD PPS proposed rule, while we continue to believe it is appropriate to tie the newness requirement to the date of the FDA marketing authorization for the reasons discussed in the CY 2020 ESRD PPS final rule, we do not believe newness should be tied to the effective date of the TPNIES policy going forward, for the reasons discussed below. In addition, we believe this eligibility criterion should address when an equipment or supply is no longer considered new. Under the current requirement at § 413.236(b)(2), we could receive an application for the TPNIES for equipment and supplies many years after FDA marketing authorization, when the equipment is no longer new.

In the CY 2020 ESRD PPS proposed rule (84 FR 38353), while we proposed to define new renal dialysis equipment

and supplies as those that are granted marketing authorization by FDA on or after January 1, 2020, we also solicited comment on whether a different FDA marketing authorization date, for example, on or after January 1, 2019, might be appropriate. We explained in the CY 2020 ESRD PPS final rule (84 FR 60688 through 60689) that while some commenters expressed support for the proposed definition, most of the comments were focused on the merits of establishing a date for newness that precedes the effective date of the TPNIES policy and whether all renal dialysis equipment and supplies must seek FDA marketing authorization. None of the comments addressed whether tying TPNIES eligibility to the TPNIES policy effective date or any fixed date would limit the TPNIES to new and innovative equipment and supplies.

After careful consideration of these comments, in the CY 2020 ESRD PPS final rule, we finalized the proposed definition of new to mean the renal dialysis equipment or supply was granted marketing authorization by FDA on or after January 1, 2020. We stated that while we appreciated that manufacturers of renal dialysis equipment and supplies that were granted FDA marketing authorization in prior years would want these products to be eligible for the TPNIES, our goal is not to provide a payment adjustment for all the products that have received FDA marketing authorization or for products that have had limited market uptake, but rather to establish an add-on payment adjustment for certain new and innovative products in order to support uptake by ESRD facilities of new and innovative renal dialysis equipment and supplies. In addition, we stated in the CY 2020 ESRD PPS final rule that we appreciated the complex issues the commenters raised if we were to select an earlier FDA marketing authorization date, and believed our approach will avoid the need to address those issues. We noted that the ESRD PPS is a prospective payment system, in which changes are generally made prospectively, including eligibility requirements for add-on payment adjustments. In addition, we noted that this FDA marketing authorization date of January 1, 2020 or later is consistent with the TDAPA's definition of a new renal dialysis drug or biological product.

As we stated in the CY 2021 ESRD PPS proposed rule (85 FR 42142 through 42143), we no longer believe an item should be considered new, based on the TPNIES policy effective date of January 1, 2020. Rather, we believe that it is important for the TPNIES policy to provide a window of time when a new renal dialysis equipment or supply is considered new to provide transparency to potential applicants. We noted that, under the proposal, the TPNIES policy would still be effective as of January 1, 2020 and therefore no equipment or supply receiving FDA marketing authorization before January 1, 2020 would be eligible for the TPNIES. However, we proposed to revise § 413.236(b)(2) to remove ''on or after January 1, 2020'' and to reflect the definition of new to mean, within 3 years beginning on the date of FDA marketing authorization. By defining new in this manner, we would be giving entities wishing to apply for the TPNIES for their equipment or supply 3 years beginning on the date of FDA marketing authorization in which to submit their applications, while still limiting eligibility for the TPNIES to new technologies. We proposed a 3-year newness window to be consistent with the timeframes under the IPPS NTAP requirements in § 412.87(b)(2). Under the NTAP, new technologies are considered to be new for 2 to 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. We noted that under the hospital outpatient PPS the pass-through payment application for a medical device must also be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability.

In addition, we proposed to revise § 413.236(b) to remove ''For dates of service occurring on or after January 1, 2020'' and to revise § 413.236(a) to reflect the January 1, 2020 effective date of the TPNIES policy finalized in the CY 2020 ESRD PPS final rule. We also proposed other revisions to this paragraph, which are discussed in section II.B.3.b.(1) of this final rule.

We sought comment on our proposal to define new for purposes of the TPNIES eligibility as within 3 years beginning on the date of FDA marketing authorization. In addition, we stated that we understood there may be situations in which a manufacturer has FDA marketing authorization for an item, but the process of manufacturing the item has been delayed, for example, by a PHE, such as the current COVID–19 pandemic. Therefore, we also sought comment on the number of years for an item to be considered new, or if newness should be based on different criteria such as the later of marketing availability or the date of FDA marketing authorization.

Currently, § 413.236(b)(4) requires applicants for the TPNIES to have a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year. Section 413.236(c) currently requires applicants for TPNIES to have the FDA marketing authorization for the equipment or supply by September 1 prior to the particular calendar year.

After publication of the CY 2020 ESRD PPS final rule, CMS updated its HCPCS Level II coding procedures to enable shorter and more frequent HCPCS code application cycles. Beginning in January 2020, CMS implemented quarterly HCPCS code application opportunities for drugs and biological products, and biannual application opportunities for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and other non-drug, non-biological items and services.

As the Administrator of CMS announced [2] in May 2019, this change is part of CMS' broader, comprehensive initiative to foster innovation and expedite adoption of and patient access to new medical technologies. CMS' delivery on this important goal necessitated procedural changes that balance the need to code more frequently with the amount of time necessary to accurately process applications. CMS has released two documents with detailed information on the updated HCPCS Level II coding procedures, application instructions, and deadlines for 2020. Both documents, HCPCS Level II Coding Procedures [3], and HCPCS Level II Code Modification Application Instructions for the 2020 Coding Cycle [4] are available on the CMS website. Under the new guidance, coding cycles for DMEPOS items and services will occur no less frequently than biannually. For 2020, the deadline for HCPCS Level II code applications for biannual Coding Cycle 1 for DMEPOS items and services was January 6, 2020 with issuance of final code decisions occurring July 2020.

[2] *https://www.cms.gov/newsroom/press-releases/cms-outlines-comprehensive-strategy-foster-innovation-transformative-medical-technologies.*

[3] *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf.*

[4] *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2020-HCPCS-Application-and-Instructions.pdf.*

These final code decisions are effective October 1, 2020. For biannual Coding Cycle 2, the code application deadline for DMEPOS items and services is June 29, 2020 with issuance of final code decisions occurring January 2021 or earlier. These final code decisions are effective April 1, 2021. These dates are specific for 2020 and may change annually. Specific dates for biannual Coding Cycles 1 and 2 for future years will be published on the HCPCS website annually.

Under the new biannual Coding Cycle 2 for DMEPOS items and services, in order to obtain a final HCPCS Level II code decision by January 1, 2021, the applicant must have submitted a complete HCPCS Level II code application along with the FDA marketing authorization documentation to CMS by June 29, 2020. In light of the change to biannual coding cycles, we stated in the CY 2021 ESRD PPS proposed rule that we reassessed the TPNIES eligibility criterion in § 413.236(b)(4), which is related to submission of the HCPCS Level II code application as well as § 413.236(c), which discusses the deadlines for consideration of new renal dialysis equipment or supply applications and found that they conflict with the current HCPCS Level II coding guidelines.

Because our HCPCS Level II coding guidelines require that applicants submit complete code applications for DMEPOS items and services to CMS by the deadline for biannual Coding Cycle 2 as specified in the HCPCS Level II coding guidance on the CMS website in order for a final HCPCS Level II code decision to be made by the following January 1 and require that documentation of FDA marketing authorization be submitted by the applicant to CMS by the HCPCS Level II code application deadline, we proposed to align the TPNIES regulation at § 413.236(b)(4) and (c) with these guidelines. We stated in the CY 2021 ESRD PPS proposed rule (85 FR 42144) that we believe this alignment would provide consistency across CMS processes and transparency on deadlines for applicants for the TPNIES. We further stated that in the event of a delay in the final HCPCS Level II coding decision, a miscellaneous code will be used in the interim until a final coding decision is made.

We also proposed to correct a technical error in § 413.236(b)(4), which requires the HCPCS application to be submitted by September 1 ''of'' the particular calendar year, meaning the year in which the payment adjustment would take effect. As we explained in the CY 2021 ESRD PPS proposed rule (85 FR 42144), in accordance with the TPNIES policy, we would need to have the HCPCS application submitted ''prior to'' the particular calendar year to be able to make a determination of TPNIES eligibility for payment to occur in the particular calendar year.

Therefore, we proposed to revise § 413.236(b)(4) to add the word ''complete'' and to replace ''September 1'' with ''the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website,'' and replace the word ''of'' with ''prior to'' to reflect that the HCPCS code application for biannual Coding Cycle 2 must be complete and submitted as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year. We explained in the CY 2021 ESRD PPS proposed rule that this HCPCS application submission deadline for a HCPCS Level II code application may result in a final HCPCS code determination by January 1, when the TPNIES payment would begin. We noted that, for 2020 biannual Coding Cycle 2, final decisions on HCPCS Level II codes issued by January 1, 2021 are not effective until April 1, 2021. For this reason, during this interim period, we proposed to use a miscellaneous HCPCS code to provide the TPNIES payment. We stated that in the event of a delay in the final HCPCS Level II coding decision, a miscellaneous code will be used in the interim until the later effective date. In addition, we proposed a technical change to § 413.236(b)(4) to be consistent with how CMS references the HCPCS Level II coding procedures. That is, we proposed to revise § 413.236(b)(4) from ''official Level II HCPCS coding procedures'' to ''HCPCS Level II coding procedures on the CMS website''.

In addition, we proposed to revise § 413.236(c) to replace ''September 1'' with ''the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website'' to reflect that FDA marketing authorization for the new and innovative equipment or supply must accompany the HCPCS application prior to the particular calendar year in order for the item to qualify for the TPNIES in the next calendar year. Although applicants for the TPNIES may submit a TPNIES application while the equipment or supply is undergoing the FDA marketing authorization process (since the deadline for the TPNIES application is February 1), under our proposal, FDA marketing authorization of the equipment or supply must be granted prior to the HCPCS Level II code application deadline. If FDA marketing authorization is not granted prior to the HCPCS Level II code application deadline, the TPNIES application would be denied and the applicant would need to reapply and submit an updated application by February 1 of the following year or within 3 years beginning on the date of FDA marketing authorization, in accordance with the proposed revisions to § 413.236(b)(2) discussed previously in this final rule.

Currently, § 413.236(b)(5) requires that the new equipment or supply be innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter and related guidance. As discussed previously in the CY 2021 ESRD PPS proposed rule and this final rule, § 412.87(b)(1) includes the criteria used under the IPPS NTAP to determine whether a new technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In § 413.236(b)(5) we adopted the same SCI criteria to determine if a new renal dialysis equipment or supply is innovative for purposes of the TPNIES under the ESRD PPS. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690) our intention to adopt any future modifications to the IPPS SCI criteria so that innovators would have standard criteria to meet for both settings. While we adopted the IPPS SCI criteria under § 412.87(b)(1), we did not adopt the alternative pathway for breakthrough devices (84 FR 42296) under the ESRD PPS.

In the fiscal year (FY) 2020 IPPS final rule (84 FR 42180 through 42181), CMS codified additional SCI criteria that had been included in manuals and other sub-regulatory guidance. In accordance with the reference to § 412.87(b)(1), we adopted the FY 2020 IPPS changes to the SCI criteria, and any future changes to the SCI criteria, by reference, unless and until we make any changes to the criteria through notice-and-comment rulemaking. Although the codification of the related guidance for the IPPS SCI occurred prior to the publication of the CY 2020 ESRD PPS final rule, we inadvertently included a reference to related guidance in § 413.236(b)(5). Therefore, we proposed to revise § 413.236(b)(5) to remove ''and related guidance'' to reflect that all related SCI guidance has now been incorporated into § 412.87(b)(1).

The comments and our responses to the comments on our proposed changes

to the eligibility criteria for the TPNIES are set forth below.

Comment: Several national associations of dialysis stakeholders, including organizations representing large dialysis organizations (LDO) and non-profit facilities, expressed support for the proposal to change the current definition of ''new'' to give entities wishing to apply for the TPNIES 3 years beginning on the date of FDA marketing authorization in which to submit their applications. An LDO requested that CMS monitor this window to ensure that 3 years is sufficient to allow manufacturers time to gather high-quality evidence of SCI for their technologies. However, a software company that developed a renal product that has demonstrated SCI, but was approved by the FDA almost 7 years ago, commented that 3 years is not long enough for its product to qualify for TPNIES consideration. The software company asked CMS to consider a longer period of eligibility for the TPNIES primarily because the dialysis industry is slow to uptake innovations. The company suggested that CMS could extend the window selectively if the applicant can show that an innovative technology has no other FDA-authorized counterpart with similar technology. The software company asserted that by lengthening the period of eligibility for the TPNIES program, with added criteria to maintain a high level of selectivity, CMS would allow that company and other worthy innovators to receive the TPNIES. The company asked that CMS consider making changes to the eligibility criteria for TPNIES that will open up the potential for providers to receive reimbursement for the use of technologies that can still be proven to be innovative and demonstrate SCI even though their FDA authorization is beyond the 3-year period.

Response: We appreciate the commenters' support for the proposal and want to point out that TPNIES applicants may submit an application while the equipment or supply is pending marketing authorization by the FDA, however, FDA marketing authorization must be submitted with the HCPCS application. We believe that 3 years is sufficient time for manufacturers to gather high-quality evidence of SCI for their product and establish their manufacturing, marketing, and distribution strategies. This is consistent with the period of time during which qualifying items and services under the Hospital Inpatient Prospective Payment System NTAP are considered new. We intend to monitor the process to ensure we provide the TPNIES to new and innovative renal dialysis equipment and supplies.

Regarding the suggestion that CMS extend the window of TPNIES eligibility if the applicant can show an innovative technology has no other FDA-authorized counterpart with similar technology, we thank the commenter for this input. We did not propose this policy in the CY 2021 ESRD PPS proposed rule, but will take this into consideration for future rulemaking.

Comment: Several national associations of dialysis stakeholders, including organizations representing LDOs and non-profit facilities, expressed support for the proposal to align the TPNIES with the new biannual Coding Cycle 2 application deadline as specified in the HCPCS Level II coding guidance on the CMS website. One commenter pointed out the alignment of the TPNIES and HCPCS processes can promote developer and manufacturer confidence by enabling them to better navigate multiple processes, specifically, marketing authorization at the FDA and HCPCS coding at CMS, both critical to bringing a product to market.

Response: We appreciate the support for the proposal.

Comment: We did not receive comments on the proposed technical change to § 413.236(b)(5) to remove ''and related guidance'' to reflect that all related SCI guidance has been incorporated into § 412.87(b)(1). However, several commenters expressed their views about the SCI criteria. While most commenters expressed support for the use of the SCI criteria to target the increase in Medicare payments and beneficiary coinsurance to clinically meaningful and innovative items, others stated that the criteria are overly restrictive. One commenter stated that some of the SCI criteria do not seem relevant to home dialysis machines and suggested that the user-friendly nature of these devices should be considered in the SCI criteria. Several commenters requested that CMS establish a two-way process for the review of evidence for TPNIES applicants that allows for rapid patient access to new and innovative products and that CMS provide reasonable and clear parameters in discussions with applicants on the types of evidence and studies technical expert panel reviewers want to see.

Several organizations recommended that the TPNIES process follow the NTAP program and exempt home dialysis devices classified as ''breakthrough'' by the FDA from the SCI requirement for the two-year TPNIES period. One association asserted that requiring these devices to navigate approval processes in both the FDA and CMS creates another disincentive to parties entering the kidney care arena.

Another commenter stated that evaluation of home dialysis machines is not the same as evaluation of medications by the FDA where the evidence of efficacy and safety can be readily attributed to medication exposure. The commenter noted that, in evaluating home dialysis machines, clinical outcomes cannot be so readily attributed to the machine itself because the effect of a home dialysis prescription is a complex function of three factors: The technical specifications of the machine; the dialysis prescription; and how patients and care partners interact with the machine. The commenter disagreed with an exclusive focus on clinical outcomes in evaluating TPNIES applications and suggested an approach that involves evaluation of whether the home dialysis machine improves access to home dialysis, the length of home dialysis, and clinical outcomes.

Response: We note that the SCI criteria were put into regulation with the establishment of the TPNIES in the CY 2020 ESRD PPS final rule. We did not propose changes to § 413.236(b)(5) beyond the technical change described previously or to the SCI criteria in § 412.87(b)(1). We note that, as we stated in the CY 2020 ESRD PPS final rule (84 FR 60691), since renal dialysis services are routinely furnished to hospital inpatients and outpatients, we believe the same SCI criteria should be used to assess whether a new renal dialysis equipment or supply warrants additional payment under the ESRD PPS. However, we appreciate the information provided by the commenters and will take the comments regarding SCI criteria for the TPNIES into consideration in future rulemaking.

Final Rule Action: After consideration of the comments we received, we are finalizing the changes to § 413.236(b) introductory text, (b)(2) through (5), and (c), as proposed, with the following modification. As we stated previously, we proposed to revise § 413.236(b)(4) to replace ''September 1'' with ''the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website.'' However, we inadvertently omitted the word ''items'' from the proposed regulation text. In this final rule, we are adding the word ''items'' to § 413.236(b)(4) consistent with our proposal.

3. Expansion of the TPNIES for New and Innovative Capital-Related Assets That are Home Dialysis Machines When Used in the Home for a Single Patient

a. Background

In response to the proposed expansion of the TDAPA in the CY 2019 ESRD PPS proposed rule, we received several comments regarding payment under the ESRD PPS for certain new, innovative equipment and supplies used in the treatment of ESRD. For example, as we described in the CY 2019 ESRD PPS final rule (83 FR 56972), a device manufacturer and device manufacturer association asked CMS to establish a transitional add-on payment adjustment for new FDA devices that have received FDA marketing authorization. They commented on the lack of new devices that have received FDA marketing authorization for use in an ESRD facility, highlighting the need to promote dialysis device innovation.

Other commenters, including a professional association and a LDO urged CMS and other relevant policymakers to prioritize the development of a clear pathway to add new devices to the ESRD PPS bundled payment (83 FR 56973). A home dialysis patient group also expressed concern regarding the absence of a pathway for adding new devices to the ESRD PPS bundled payment, stating that it left investors and industry wary of investing in the development of new devices for patients. In response, we expressed appreciation for the commenters' thoughts regarding payment for new and innovative devices, and stated that because we did not include any proposals regarding this issue in the CY 2019 ESRD PPS proposed rule, we considered these suggestions to be beyond the scope of that rule.

However, in response to this feedback, in the CY 2020 ESRD PPS proposed rule (84 FR 38354 through 38355), we agreed that additional payment for certain renal dialysis equipment and supplies may be warranted under specific circumstances. We proposed to provide the TPNIES for certain new and innovative renal dialysis equipment and supplies furnished by ESRD facilities, but excluded from eligibility capital-related assets, which are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). The Provider Reimbursement Manual is available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.* Examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems.

As we explained in the CY 2020 ESRD PPS proposed rule (84 FR 38354), we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and they are generally used for multiple patients. In addition, we noted that since the costs of these items are reported in the aggregate, there is considerable complexity in establishing a cost on a per treatment basis. For these reasons, we therefore believed capital-related assets should be excluded from eligibility for the TPNIES at that time, and we proposed an exclusion to the eligibility criteria in § 413.236(b)(6). However, we noted that CMS uses capital-related asset cost data from cost reports in regression analyses to refine the ESRD PPS so that the cost of any new capital-related assets is accounted for in the ESRD PPS payment.

In response to the proposed exclusion of capital-related assets, we received comments from a device manufacturers' association, which stated that since most medical equipment is purchased as a capital-related asset, the TPNIES effectively would exclude the innovative equipment identified in the title of the adjustment. The association asserted that meaningful clinical improvements and patient experience improvements are arguably more likely to come from innovation outside single-use supplies. The association maintained that expanding the TPNIES to include medical equipment, regardless of how it is purchased by the provider, would stimulate greater investment in a broader array of new technologies for ESRD patients.

In response, we stated in the CY 2020 ESRD PPS final rule (84 FR 60688) that we recognize that accounting for renal dialysis service equipment can vary depending on the individual ESRD facility's business model. For example, when the owner of the capital-related asset retains title, then the renal dialysis service equipment is a depreciable asset and depreciation expense could be itemized. When there is no ownership of the renal dialysis service equipment, then the item is recorded as an operating expense.

In addition, in response to comments regarding capital leases, we noted that regulations at § 413.130(b)(1) specify that leases and rentals are includable in capital-related costs if they relate to the use of assets that would be depreciable if the provider owned them outright. We stated that in the future, we will be closely examining the treatment of capital-related assets under Medicare, including our regulations at § 412.302 regarding capital costs in inpatient hospitals and § 413.130, as they relate to accounting for capital-related assets, including capital leases and the newly implemented guidance for finance lease arrangements, to determine if similar policies would be appropriate under the ESRD PPS.

b. Additional Payment for New and Innovative Capital-related Assets That are Home Dialysis Machines When Used in the Home for a Single Patient

Following publication of the CY 2020 ESRD PPS final rule, in which we finalized the TPNIES policy, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we received additional comments and information from dialysis equipment and supply manufacturers, and a Technical Expert Panel (TEP) meeting held in December 2019, regarding the need for additional payment for capital-related assets under the ESRD PPS.

We also took into account the President's Executive order, signed on July 10, 2019, aimed at transforming kidney care in America. The Executive order discussed many new initiatives, including the launch of a public awareness campaign to prevent patients from going into kidney failure and proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease and encouraging the development of breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available. Currently, most dialysis is furnished at ESRD facilities. In-center dialysis can be time-consuming and burdensome for patients. In addition, the current system prioritizes payment to in-center dialysis and the goal of the agency is to incentivize in-home dialysis. A key focus of the Executive order is the effort to encourage in-home dialysis.

The Executive order is available at: *https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/.*

In conjunction with the Executive order, HHS laid out three goals for improving kidney health (see *https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-*

advancing-american-kidney-health-initiative.html):

- Reducing the number of Americans developing ESRD by 25 percent by 2030.
- Having 80 percent of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant; and
- Doubling the number of kidneys available for transplant by 2030.

In addition, in connection with the President's Executive order, on July 10, 2019, CMS issued a proposed rule (84 FR 34478) to implement a new mandatory payment model, known as the ESRD Treatment Choices (ETC) Model, which would provide new incentives to encourage the provision of dialysis in the home. The ETC Model, which CMS finalized in a final rule published in the **Federal Register** on September 29, 2020 (85 FR 61114), is a mandatory payment model, focused on encouraging greater use of home dialysis and kidney transplants for ESRD beneficiaries among ESRD facilities and Managing Clinicians located in selected geographic areas.

Lastly, as we noted in the CY 2021 ESRD PPS proposed rule, ESRD patients who receive in-center dialysis are particularly vulnerable during a PHE and other disasters, and greater use of home dialysis modalities may expose these patients to less risk. The U.S. is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that was first detected in China and which has now been detected in more than 215 countries internationally, and all 50 states and the District of Columbia. The virus has been named ''severe acute respiratory syndrome coronavirus 2'' (SARS–CoV–2) and the disease it causes has been named ''coronavirus disease 2019'' ('COVID–19').

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of international concern.'' On January 31, 2020, the Secretary determined that a PHE exists for the U.S. to aid the nation's healthcare community in responding to COVID–19 and on April 21, 2020, the Secretary renewed, effective April 26, 2020, the determination that a PHE exists. On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President of the U.S. declared the COVID–19 pandemic a national emergency.

As we discussed in the CY 2021 ESRD PPS proposed rule, the experience of multiple countries across the globe has demonstrated that older patients and patients with multiple comorbidities and underlying health conditions are patients who are more susceptible to the virus and have a higher risk of morbidity than younger patients without underlying health conditions. Per the CDC, the risk factors for COVID–19 include older adults and people of any age who have serious underlying medical conditions, such as diabetes and chronic kidney disease undergoing dialysis. Medicare's ESRD population aligns with the profile of patients who are more susceptible to COVID–19. Therefore, it is important to reduce the risk of infection and this can be done through isolating patients from in-center exposure by encouraging home dialysis.

We also noted that home dialysis would mitigate the risks associated with dialysis for these patients if the pandemic lasts longer than expected or is refractory in some way.

(1) Expansion of the TPNIES to Certain New and Innovative Capital-Related Assets That are Home Dialysis Machines When Used in the Home for a Single Patient

In response to the President's Executive order, the various HHS home dialysis initiatives, and the particular benefits of home dialysis for ESRD beneficiaries during PHEs like the current COVID–19 pandemic, which we discussed in the previous section, and in consideration of the feedback we have received from stakeholders, we stated in the CY 2021 ESRD PPS proposed rule that we agree that additional payment through the TPNIES for certain capital-related assets may be warranted under specific circumstances outlined in the proposed rule. We noted that in the CY 2020 ESRD PPS final rule (84 FR 60607), we specifically excluded capital-related assets from the TPNIES. In commenting on the CY 2020 ESRD PPS proposed rule, most stakeholders expressed concern that the TPNIES would exclude capital-related assets. In our response to commenters, we acknowledged that significant innovation and technology improvement is occurring with dialysis machines and peritoneal dialysis (PD) cyclers, as well as innovation in the efficiency and effectiveness of water systems. However, at that time we did not have enough information regarding current usage of the various financial and leasing arrangements, such as those involving capital leases for depreciable assets versus operating leases recorded as operating expenses. In addition, we noted that we would need to assess methodological issues regarding depreciation to determine whether TPNIES eligibility for these items would be appropriate.

We stated in the CY 2020 ESRD PPS final rule that we needed to further study the specifics of the various business arrangements for equipment related to renal dialysis services. This would include items that are: (1) Purchased in their entirety and owned as capital-related assets; (2) assets that are acquired through a capital lease arrangement; (3) equipment obtained through a finance lease and recorded as an asset per the Financial Accounting Standards Board (FASB) guidance on leases (Topic 842) effective for fiscal years beginning after December 15, 2018; [5] or (4) equipment obtained through an operating lease and recorded as an operating expense. In addition to the variety of business arrangements, we noted, there are unknown issues relating to ownership of the item and who retains title, which may affect the equipment's maintenance expenses for capital-related assets.

Further, we noted the issue of single use versus multiple use for capital-related assets used for renal dialysis services. For example, some capital-related assets used in-center and in the home setting, such as skilled nursing facilities (SNFs) and nursing facilities, may be used by multiple patients in a day, and by multiple patients over their useful lifetime. Specifically, equipment classified as capital-related assets may be refurbished and used by another patient. For example, capital-related assets used by multiple patients in a day could be Hoyer lifts to transfer patients and wheelchair scales. In the CY 2021 ESRD PPS proposed rule, we did not propose to include capital-related assets with multi-patient usage as being eligible for the TPNIES because we aimed to support the President's Executive order and HHS goals of promoting home dialysis, which involves a single machine for patient use. In addition, as we discussed earlier in this section, it is more complicated to develop a per treatment payment amount for those items. However, we sought comments on this aspect of our proposal, and stated our intention to gather additional information about how ESRD facilities obtain their capital-related assets that have multi-patient usage in future meetings with the TEP.

We stated in the CY 2021 ESRD PPS proposed rule that as we further studied this issue, we determined that one business arrangement, that is, where the capital-related assets are purchased in their entirety and owned as capital-related assets, could be considered for

[5] *https://www.fasb.org/jsp/FASB/Document_C/DocumentPage?cid=1176167901010&acceptedDisclaimer=true.*

TPNIES eligibility. We noted that we continued to analyze other business arrangements, but we understood this arrangement is more straightforward due to ownership being clear, retained at the end of the TPNIES period, and on the facility's balance sheet. CMS' intent would be to pay for assets that are owned, whether purchased or attained through a capital lease. The entity who holds the title to the asset is the legal owner. At the end of the TPNIES period, the entity retains ownership of the asset. We stated we would not pay the TPNIES for equipment that is leased, as the ESRD facility has no ownership rights. We stated that we believe this is an appropriate initial step to support home dialysis.

In support of the HHS goals and initiatives to increase home dialysis following the President's Executive order, we proposed to provide the TPNIES for eligible new and innovative capital-related assets that are home dialysis machines when used in the home. We would limit the payment for new and innovative dialysis machines to those used for home dialysis in order to target the additional payment through the TPNIES to equipment that supports the various home dialysis initiatives currently underway, as discussed previously in the CY 2021 ESRD PPS proposed rule and this section of this final rule. As more ESRD patients and their nephrologists and other clinicians opt for home dialysis modalities, we would seek to support ESRD facility use and beneficiary access to the latest technological improvements to HD and PD home dialysis machines. As we explained in prior ESRD PPS rules establishing the TDAPA and TPNIES, ESRD facilities face unique challenges in incorporating new renal dialysis drugs, biological products, equipment and supplies into their businesses and these add-on payment adjustments are intended to support ESRD facilities' use of new technologies during the uptake period for these new products.

To codify our proposals for expanding the TPNIES to include capital-related assets that are home dialysis machines when used in the home for a single patient, we proposed further revisions to § 413.236, in addition to the revisions finalized earlier in section II.B.2 of this final rule.

Specifically, we proposed to revise the heading at § 413.236(a) and add paragraphs (a)(1) and (2) to distinguish this paragraph as both the ''basis and definitions.'' We proposed to define ''capital-related asset'' at § 413.236(a)(2) as an asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets. This proposed definition was based on the definition of ''depreciable assets'' in the Provider Reimbursement Manual (chapter 1, section 104.1). The Provider Reimbursement Manual is available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

We proposed to define ''home dialysis machines'' at § 413.236(a)(2) as hemodialysis machines and peritoneal dialysis cyclers in their entirety, meaning that one new part of a machine does not make the entire capital-related asset new, that receive FDA marketing authorization for home use and when used in the home for a single patient. FDA provides a separate marketing authorization for equipment intended for home use, and our proposal was focused on supporting efforts to increase home dialysis.

We proposed to define ''particular calendar year'' at § 413.236(a)(2) as the year in which the payment adjustment specified in paragraph (d) of § 413.236 would take effect. We also proposed to include definitions for the terms ''depreciation,'' ''straight-line depreciation method,'' and ''useful life,'' which are discussed in section II.B.3.b.(2) of this final rule.

We proposed to revise § 413.236(b)(6) to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in § 413.236(b). We also proposed to remove ''that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired)'' in § 413.236(b)(6) since we proposed a separate definition for ''capital-related asset'' at § 413.236(a)(2).

Under the proposal, we continued to exclude other capital-related assets from the TPNIES that are not home dialysis machines when used in the home because those items would not be advancing HHS's goal of increasing home dialysis. Examples of capital-related assets that would continue to be excluded from TPNIES are water purification systems and dialysis machines when they are used in-center. We stated that we continue to believe we should not provide additional payment for these capital-related assets because the cost of these items are captured in cost reports and reported in the aggregate, depreciate over time, are generally used for multiple patients and, most importantly, it would not support the goal of increasing use of home dialysis. However, capital-related assets that are home dialysis machines when used in the home are intended for use by a single patient and can be reported on a per treatment basis on the ESRD facility's claim. These characteristics provide for a simple methodology for aligning the use of the asset with the per treatment TPNIES payment.

As we stated previously in this section, we did not propose to expand the TPNIES eligibility to in-center dialysis machines or home dialysis machines when they are used in-center. Currently, our focus is promoting the increase in home dialysis rather than in-center dialysis. In addition, in-center dialysis machines are used by multiple patients each day and would require additional analysis, along with 72X claims and cost report modifications, in order to provide payment. For this same reason, we did not propose to provide the TPNIES for home dialysis machines when they are used in SNFs and nursing facilities that are used by multiple patients each day.

We stated in the CY 2021 ESRD PPS proposed rule that we believe the SCI criteria required under § 413.236(b)(5), with our proposed revisions, and the process used to evaluate SCI currently applicable to TPNIES equipment and supplies are also appropriate for identifying new and innovative capital-related assets that are home dialysis machines that are worthy of temporary additional payment under the ESRD PPS. This approach would provide consistent criteria and evaluation for all equipment and supplies that are potentially eligible for the TPNIES. In addition, we noted that we want to ensure we do not pay the TPNIES for new home dialysis machines that are substantially similar to existing machines and not truly innovative.

We proposed to utilize the determination process we established in the CY 2020 ESRD PPS final rule for the TPNIES and those requirements we proposed to revise in section II.B.2 of the CY 2021 ESRD PPS proposed rule. That is, pursuant to § 413.236(c), interested parties would submit all information necessary for determining that the home dialysis machine meets the TPNIES eligibility criteria listed in § 413.236(b). This would include FDA marketing authorization information, the HCPCS application information, and studies submitted as part of these two standardized processes, an approximate date of commercial availability, and any information necessary for SCI criteria evaluation. For example, clinical trials,

peer reviewed journal articles, study results, meta-analyses, systematic literature reviews, and any other appropriate information sources can be considered. We noted, for purposes of determining whether the home dialysis machine is new under § 413.236(b)(2), we would look at the date the machine is granted marketing authorization by FDA for home use.

We stated that, using our current process at § 413.236(c), we would provide a description of the new home dialysis machine and pertinent facts in the ESRD PPS proposed rule so the public may comment on them and then publish the results in this ESRD PPS final rule. We would consider whether the new home dialysis machine meets the eligibility criteria specified in the proposed revisions to § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. Per § 413.236(c), we would only consider, for additional payment using the TPNIES for a particular calendar year, an application for a capital-related asset that is a home dialysis machine we receive by February 1 prior to the particular calendar year. If the application is not received by February 1, the application would be denied and the applicant would need to reapply within 3 years beginning on the date of FDA marketing authorization in order to be considered for the TPNIES, in accordance with the proposed revisions to § 413.236(b)(2). We noted, applicants are expected to submit information on the price of their home dialysis machine as part of the TPNIES application. While we recognize this information is proprietary, CMS requests this information along with the equipment or supply's projected utilization.

For example, under our proposed revisions to § 413.236, in order for a particular home dialysis machine to be eligible for the TPNIES under the ESRD PPS beginning in CY 2022, CMS must receive a complete application meeting our requirements no later than February 1, 2021. FDA marketing authorization and submission of the HCPCS Level II code application for Coding Cycle 2 for DMEPOS items and services must occur as specified in the HCPCS Level II coding guidance on the CMS website. We would include a discussion of the new capital-related asset that is a home dialysis machine in the CY 2022 ESRD PPS proposed rule and the CMS final determination would be announced in the CY 2022 ESRD PPS final rule. If the home dialysis machine qualifies for the TPNIES, the payment adjustment would begin January 1, 2022 with a miscellaneous code and the designated HCPCS code would be effective April 1, 2022.

In accordance with § 413.236(c), the CMS TPNIES final determinations for CY 2021 are presented in section II.C of this final rule.

The comments and our responses to the comments on our proposed expansion of the TPNIES to include certain home dialysis machines are set forth below.

Comment: Most commenters generally supported expanding the eligibility for TPNIES to include capital-related assets that are home dialysis machines and provided suggestions on ways to improve the proposal. However, MedPAC and LDOs did not support the proposal. MedPAC and other commenters stated that, instead of paying the TPNIES for new home dialysis machines, CMS should address the clinical and nonclinical factors known to affect home dialysis use. They stated that CMS's proposal to expand the TPNIES as proposed would undermine the integrity of the ESRD PPS bundled payment and limit the competitive forces that generate price reductions. They stated that if CMS proceeds with the proposal, eligible equipment should be innovative and payment should not be duplicative. They urged CMS to take more time and engage the industry to develop a comprehensive policy and indicated there were more meaningful ways to support the Executive order. One LDO commented that access to home dialysis machines is not currently a roadblock to home therapy, and proposed add-on payments to purchase home machines will not address any of the real barriers to home dialysis or further the goals of the Executive order. Another LDO expressed concerns about the proposed exclusion of dialysis machines used in-center and urged CMS to expand the capital-related assets policy before it is finalized.

However, several device manufacturers and a home dialysis patient organization urged CMS to not make patients wait over a year to have access to the newest innovative home dialysis machines. Instead, they proposed that CMS, in the final rule, allow a new application submission period to consider applicants under the capital-related home dialysis machines pathway for eligibility for payment beginning April 1, 2021, and provide for a 30-day comment period. They believe proceeding in such a way would satisfy the Administrative Procedure Act requirements for notice and comment and put CMS on a faster pathway to success in meeting the rapidly growing demand from patients for home dialysis, given the COVID–19 pandemic, by providing them with new options to perform treatments safely and easily in their homes. The patient organization noted that patients need choices and, currently, if a patient fails to thrive on a home dialysis machine, often the patient has no choice but to return to in-center dialysis. The patient organization stated that new home dialysis machines in the pipeline will be critical to achieving the Executive order goal of moving dialysis patients home. Another commenter urged CMS to act boldly and without delay.

Response: In order to support the goals of the Executive order, we believe that providing the TPNIES for new and innovative home dialysis machines is a good start because it will increase home dialysis by leading to technological change in those machines, which will make a difference in patient-related outcomes and long-term adherence to home dialysis. For example, beneficiary feedback reveals that one of the most significant drawbacks to home dialysis is fear of self-cannulation; despite training, this remains a significant drawback. A new and innovative home dialysis machine that is able to cannulate the dialysis recipient would substantially improve the treatment of ESRD beneficiaries and be a huge advancement toward increasing home dialysis.

With regard to the suggestion that we issue the final rule with a comment period in order to accept new applications for capital-related home dialysis machines for payment eligibility beginning April 1, 2021, we note that our process of evaluating substantial clinical improvement is lengthy. An IFC published in November 2020, and accepting applications for capital-related assets that are home dialysis machines used in the home by February 1, 2021, with a payment eligibility date of April 1, 2021 would not provide adequate time for review of SCI. We note that a commenter indicated there at least 3 home dialysis machines currently under development. Providing eligibility for home dialysis machines earlier than our proposed effective date would give an unfair advantage to the current applicant that has already received FDA marketing authorization for home use. Had the other companies known about an earlier effective date, they may have altered their testing protocols and marketing plans. We thank MedPAC and the LDOs for their comments and share their concern about maintaining the integrity of the ESRD PPS bundled payment. We have tried to strike a balance between supporting the uptake of new and

innovative home dialysis machines that demonstrate substantial clinical improvement, while maintaining the integrity of the ESRD PPS bundled payment. As discussed later in this section, as part of our final methodology, we are offsetting the TPNIES payment for home dialysis machines used in the home by $9.32, the amount currently included in the base rate for the dialysis machine. Regarding the expansion of capital-related assets to include in-center dialysis machines, at this time we are striving to support the Executive order for payment incentives for greater use of home dialysis.

Comment: Several commenters, including both LDOs and small dialysis organizations, asked CMS to affirm in the final rule that the TPNIES will attach to the device and not to the initial patient utilizing the device. They acknowledged that CMS seeks to develop a policy for home dialysis machines that are used by a single patient, however, they pointed out that it is the current standard of care and practice that such home dialysis machines are repurposed during their lifetimes to serve successive patients who have the exclusive use of the machine while it is in the patient's custody. They asked CMS to affirm in the final rule that a facility may continue to claim the TPNIES for that specific device until the facility reaches the maximum allowable TPNIES amount pursuant to the adopted methodology.

The organization of LDOs also recommended that CMS modify the policy to ensure that ESRD facilities are held harmless for missed treatments. The commenter stated that the proposed methodology ties TPNIES to the per-treatment claim for a patient. If a patient misses a treatment, whether due to personal choice, hospitalization, travel, or otherwise, the facility will lose a portion of the TPNIES payment. They suggested that CMS consider an alternate methodology that would allow providers to continue to claim these TPNIES payments for missed treatments. For example, they suggested that CMS could allow each facility to continue to claim the TPNIES payment on an ongoing basis until the facility reaches the maximum allowable TPNIES amount pursuant to the adopted methodology.

Response: The TPNIES is paid based on the HCPCS code and as such is attached to the device, when the HCPCS code is billed. In addition, we are aware that patients may, for various reasons, no longer require the home dialysis machine, or may become unable to do home dialysis, and that, when a patient no longer uses the home dialysis machine, the machine may be refurbished and given to another home patient. With regard to the suggestion that facilities bill Medicare for the machine even though it wasn't used because the treatment was not furnished, it is not appropriate for payment purposes since payment is only made for services furnished and when the device is used. Such an approach would not comport with the False Claims Act. We note that the calculated TPNIES amount based on the invoice, is not a guarantee for a maximum allowable reimbursement. Payment is tied to the dialysis treatment provided. If the machine is purchased and not used in a treatment, the TPNIES is not paid. The TPNIES is a payment adjustment to the ESRD PPS base rate and is dependent on the ESRD facility providing the dialysis treatment.

Comment: One commenter stated that although the phrase ''in the home for a single patient'' is clear, the phrase causes confusion about whether CMS is encouraging on-site dialysis in a SNF. The commenter noted that in the ESRD Treatment Choices payment model proposal, CMS included condition code 80 (home dialysis furnished in a SNF or nursing facility) in its definition of home dialysis, suggesting that CMS recognizes that dialysis in a SNF ought to be classified as home dialysis—on par with home dialysis in a private residence. However, the commenter stated that CMS's proposal seems to take the position that the TPNIES expansion will not apply to on-site dialysis in the SNF, apparently because a single machine there may be used by multiple patients. The commenter recommended that, if the concern is that a single machine may be used by multiple patients, resulting in excess payment to the ESRD facility, then CMS could reduce the TPNIES amount by a factor commensurate with the average number of treated patients per machine. The commenter stated that it is in the interest of CMS and patients alike to promote on-site dialysis in the SNF and recommended using the TPNIES expansion to do so.

Response: It is our longstanding policy [6] [7] under the ESRD PPS (and the composite rate system that preceded it) that a skilled nursing facility (SNF) or a nursing facility (NF) can be considered a patient's home for dialysis. As a result, ESRD facilities may furnish home dialysis to individual patients who are residing in these facilities. Therefore, for purposes of the TPNIES, our longstanding policy holds. That is, ESRD facilities may furnish home dialysis to patients residing in SNFs and NFs, and we would provide the TPNIES for home dialysis machines when they are used in SNFs and NFs and are used by a single patient. Per the 1981 Committee on United States Senate Finance Report,[8] home dialysis machines were intended for single patient use. While we have provided additional flexibilities [9] [10] during the current PHE for ESRD facilities to furnish in-center dialysis to groups of ESRD patients residing in SNFs or NFs, we would not provide the TPNIES for the use of home dialysis machines for multiple patients.

Comment: We received comments from stakeholders across the ESRD industry asking that CMS consider other factors that are critical to successful home dialysis as we assess innovative home dialysis machines for TPNIES eligibility. For example, one commenter stated that some of these machines may require patients to have internet and broadband services so that data can easily transfer from the patient's home to the ESRD facility managing the home dialysis. The commenter stated that in rural areas particularly, access to internet and broadband services may be challenging and patients in rural areas in many ways could most benefit from new access to innovative home dialysis machines, which could help them avoid frequent extended travel times to and from ESRD facilities to receive in-center treatment.

Another commenter recommended expansion of the TPNIES to include water and sewer systems, explaining that innovation in the efficiency and effectiveness of water systems would both improve patient quality of care, as well as reduce costs for facilities and reduce the amount of water that ESRD facilities currently waste, helping to preserve the nation's water supply.

One organization expressed appreciation that CMS is refining TPNIES and considering ways to include some capital-related assets in the TPNIES policy, but stated the final rule should recognize the option for other capital-related assets to qualify for the TPNIES potentially in the future. The organization asked that CMS gather

[6] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-24-ESRD.pdf.*

[7] *https://ecfr.io/Title-42/Section-494.100.*

[8] *https://www.finance.senate.gov/imo/media/doc/SPrt97-9.pdf.*

[9] *https://www.cms.gov/files/document/qso-20-19-esrd-revised.pdf.*

[10] *https://www.cms.gov/files/document/covid-19-esrd-facilities.pdf.*

additional information about home dialysis machines that may be eligible for the TPNIES, as well as other types of capital-related assets, and construct a policy that supports the TPNIES for more than one narrow type of product. The organization suggested that we seek additional information about how ESRD facilities obtain their capital-related assets that have multi-patient usage through a request for information, as well as convening a technical expert panel(s).

An LDO and LDO organization stated that the TPNIES policy should be focused on transition payment for new equipment that represents SCI, and not skewed by site of service. They stated that to combine the requirement for SCI with an in-home only requirement would likely discourage investment in new technology, undercutting the entire TPNIES policy. They also agreed, stating that the ESRD program's fundamental purpose is to service all patients. The LDO urged CMS not to establish a policy that benefits only those ESRD patients who are clinically suited for and have the social support structure necessary to elect home dialysis. Rather, CMS should adopt a comprehensive TPNIES capital-related expenses policy that supports technological advances across all treatment modalities and provides adequate and sustained payment upon a TPNIES's expiration. They encouraged CMS to establish a working group or a TEP to inform the development of a broader TPNIES eligibility to include in-center capital-related assets.

We received many comments from patient groups, device manufacturers, dialysis organizations, health plans and a pharmacy regarding the requirement that the home dialysis machine must be owned by the ESRD facility and not leased equipment. One commenter stated that financial incentives for acquiring breakthrough dialysis innovations should not be limited only to the facilities that have the financial reserves to outright purchase this equipment, that is, the larger dialysis providers in the marketplace. They stated that smaller and medium-size ESRD facilities may lack the capital to be able to purchase the latest home dialysis technologies, and thus may prefer to rely on operating leases to obtain it.

A pharmacy stated that smaller and medium-size facilities and their patients must not be disadvantaged compared to larger facilities with regard to financial incentives to propel use of the latest, clinically optimal home dialysis equipment. The pharmacy commented that facilities might choose to obtain the new home dialysis devices via operating leases because technical support services are available under that arrangement, which benefits both the facility and the patient. In addition, operating leases can provide clinics the ability to more quickly scale and increase the volume of available new devices, as more patients choose home therapies. They believe these business arrangements complement the accelerated trend toward home dialysis, and therefore should be supported under the TPNIES policy. Another commenter urged CMS to consider business arrangements other than outright purchase of home dialysis machines and equipment, stating that many facilities maintain subscriptions with manufacturers or lease equipment, and the commenter believes that these arrangements should be accounted for under TPNIES.

Response: We thank the commenters for their suggestions. We will take these suggestions under consideration for future rulemaking. We believe it is appropriate to implement a narrow capital-related asset eligibility under the TPNIES at this time to advance the goals of the Executive order. We believe we will gain valuable information through implementation of the TPNIES for home dialysis machines that are owned in their entirety by the ESRD facility and used for a single patient. We are continuing to analyze and consider how to account for depreciation for multi-patient use machines and other capital-related assets, such as water and sewer systems. We will also consider the commenters' suggestion regarding a TEP or RFI to get information from ESRD facilities about the machines they use and how they acquire them.

When there is no ownership of the renal dialysis service equipment, then the item is recorded as an operating expense. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets. The proposed definition of capital-related assets is based on the definition of ''depreciable assets'' in the Provider Reimbursement Manual (chapter 1, section 104.1). The Provider Reimbursement Manual is available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.* We did not propose to make an add-on payment adjustment for operating expenses, but appreciate the suggestion and will consider it in future rulemaking.

We appreciate the suggestions that we consider other factors than SCI for TPNIES eligibility and allow the TPNIES for in-center treatments. While we considered other factors than SCI for TPNIES eligibility, our focus on the beneficiary and clinical improvement was a primary factor. As we stated previously in the background section of this final rule, at this point we believe it is important we use the same criteria used under the NTAP so there are consistent standards for manufacturers and CMS. At this time, our focus is on supporting the goals of the Executive order to increase home dialysis as opposed to in-center dialysis.

Comment: A health plan expressed appreciation for CMS's efforts to encourage innovation through new technology payments, and especially supported the proposed addition of in-home dialysis equipment to the TPNIES program, as there has been very little innovation in this arena in the past decade. However, the health plan expressed concern about the financial barriers to ESRD facilities adopting new technology. As an example, the commenter stated that the Tablo® Hemodialysis System described in section II.C of this final rule can cost approximately $40,000 which is twice the cost of alternative home dialysis systems. The health plan explained that, although there may be benefits to the new Tablo® system, the cost is financially prohibitive to many small ESRD facilities. Even if the system (or components of the system) are approved for the new technology add-on payment adjustment, CMS will only pay for 65 percent of the cost, leaving the remainder to be covered by the dialysis provider. They stated that this arrangement will be cost-prohibitive for most small and rural dialysis providers and will discourage the use of new technology. The health plan is also concerned that providing new technology add-on payment adjustments will discourage other companies from developing similar, less expensive alternatives until the add-on period has ended. They believe it is imperative for CMS to encourage both competition and innovation.

Response: The intent of the TPNIES is to support ESRD facilities in the uptake of new and innovative equipment and supplies under the ESRD PPS that provide substantial clinical improvements to patients, which will facilitate beneficiary access to those renal dialysis equipment and supplies. Additionally, consistent with CMS's longstanding goals, our goal with the TPNIES policy is to support better care at lower costs. We expect ESRD facilities to be judicious in the selection of new machines, balancing the cost of the machine with the promised clinical

improvement the machine would provide. We also expect increased competition for market share through both lower acquisition costs and TPNIES dollars will enhance access to machines providing clinical improvement for ESRD patients. We disagree that improvements would not occur when the TPNIES is being paid for a particular home dialysis machine. We anticipate that manufacturers will continue to develop equipment that can compete for market share. While we do not control what manufacturers charge ESRD facilities, as new machines in the development pipeline come to market, there is likely to be significant competition among manufacturers which should lead to lower prices as the manufacturers compete for the home dialysis market.

Comment: Another commenter strongly encouraged CMS to include the perspectives of current home dialysis patients in its evaluation of new home dialysis machines. The commenter stated that CMS staff, nephrologists, allied health care professionals, and epidemiologists cannot collectively evaluate whether machines are truly innovative and truly life-changing if patient perspectives are not solicited. The commenter stated that, while patients are often invited to submit letters during a public comment period following a proposed rule at the behest of manufacturers, these letters often involve formulaic content, not personal perspectives. The commenter asserted that most patients are unaware of rulemaking and do not submit comments. The commenter advised CMS to convene a TEP that includes patients to evaluate each application and encouraged town hall forums for active patient input.

Response: We appreciate the commenter's input regarding patient perspective. The TPNIES payment was modeled after the IPPS NTAP system, which process includes a public meeting. We did not have a public meeting as part of the TPNIES this first year, but a public meeting for future TPNIES applications could draw the patient participation and perspective the commenter suggests and we will consider adding a patient representative to the workgroup that reviews TPNIES applications in future rulemaking.

Final Rule Action: After consideration of public comments, we are finalizing the revision to § 413.236(b)(6) to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in § 413.236(b), as proposed. We are also finalizing the revision to the heading at § 413.236(a) and the addition of the paragraphs (a)(1) and (2) to distinguish this paragraph as both the ''basis and definitions.'' We are finalizing the definitions for ''capital-related asset,'' ''depreciable assets,'' ''particular calendar year,'' ''depreciation,'' ''straight-line depreciation method,'' and ''useful life,'' which are discussed in section II.B.3.b.(2) of this final rule, as proposed. With regard to the definition of ''home dialysis machines,'' we are revising the proposed definition to include parentheses to make the sentence more readable in the preamble and the regulation text.

We are also finalizing the removal of ''that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired)'' in § 413.236(b)(6), as proposed, since we are finalizing a separate definition for ''capital-related asset'' at § 413.236(a)(2) as discussed below.

(2) Pricing of New and Innovative Capital-Related Assets That are Home Dialysis Machines When Used in the Home

As we explained in the CY 2020 ESRD PPS final rule (84 FR 60692), we are not aware of pricing compendia currently available to price renal dialysis equipment and supplies for the TPNIES. We also noted that, unlike new renal dialysis drugs and biological products eligible for the TDAPA, ASP and WAC pricing do not exist for renal dialysis equipment and supplies, including capital-related assets that are home dialysis machines.

In addition, as we explained in the CY 2020 ESRD PPS final rule (84 FR 60692), ESRD facility charges are gross values; that is, charges before the application of allowances and discounts deductions. We believe the TPNIES payment amount should reflect the discounts, rebates and other allowances the ESRD facility (or its parent company) receives. These terms are defined in the Provider Reimbursement Manual (chapter 8).[11] If the TPNIES payment amount does not reflect discounts, rebates and other allowances, the price would likely exceed the facility's cost for the item and result in higher co-insurance obligations for beneficiaries.

For this reason, in § 413.236(e), we established an invoice-based approach for MACs to use on behalf of CMS to price new and innovative renal dialysis equipment and supplies that meet the eligibility criteria for the TPNIES. We require the MACs to establish a price, using verifiable information from the following sources of information, if available: (1) The invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant. As discussed in the CY 2020 ESRD PPS final rule (84 FR 60692 through 60693), in order to maintain consistency with the IPPS NTAP payment policy and to mitigate the Medicare expenditures incurred as a result of the TPNIES, we finalized a policy at § 413.236(d) to base the TPNIES payment on 65 percent of the MAC-determined price.

As we explained in the CY 2021 ESRD PPS proposed rule (85 FR 42148 through 42149), we believe that the invoice-based approach established for the TPNIES also should be applied to capital-related assets that are home dialysis machines, which are the focus of the TPNIES expansion. However, capital-related assets that are home dialysis machines when used in the home for a single patient are depreciable assets as defined in the Provider Reimbursement Manual (chapter 1, section 104), which defines depreciation as ''that amount which represents a portion of the depreciable asset's cost or other basis which is allocable to a period of operation.'' The Provider Reimbursement Manual provides the American Institute of Certified Public Accountant's definition of depreciation as a process of cost allocation: ''Depreciation accounting is a system of accounting which aims to distribute the cost or other basic value of tangible capital assets, less salvage (if any), over the estimated useful life of the unit (which may be a group of assets) in a systematic and rational manner. It is a process of allocation, not of valuation. Depreciation for the year is the portion of the total charge under such a system that is allocated to the year.''

Because capital-related assets that are home dialysis machines when used in the home for a single patient are depreciable assets, we proposed to apply a 5-year straight-line depreciation method to determine the basis of the TPNIES for these items. The Provider Reimbursement Manual (chapter 1,

[11] Medicare Provider Reimbursement Manual (chapter 8). Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R450PR1.pdf.*

section 116.1) discusses the straight-line depreciation method as a method where the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life. Section 104.17 of the Provider Reimbursement Manual discusses that the useful life of a capital-related asset is its expected useful life to the provider, not necessarily the inherent useful or physical life. Further, the manual provides that under the Medicare program, only the American Hospital Association (AHA) guidelines may be used in selecting a proper useful life for computing depreciation.

Using the Provider Reimbursement Manual definitions as the basis, we proposed to define the following terms at § 413.236(a)(2): ''depreciation'' as the amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation; ''straight-line depreciation method'' as a method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life; and ''useful life'' as the estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

In keeping with the Medicare policy, we proposed to rely on the AHA guidelines to determine the useful life of a capital-related asset that is a home dialysis machine. That is, the useful life of a home dialysis machine is 5 years. Since we proposed a methodology using the Provider Reimbursement Manual's guidance, we believe these terms are appropriate to codify for purposes of calculating the price of a home dialysis machine that is a capital-related asset. That is, under § 413.236(e), MACs, on behalf of CMS, would establish prices, using verifiable information as described above, for new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient that meet the eligibility criteria specified in § 413.236(b). This price would be the only element used to determine the total cost basis for applying the straight-line depreciation method. For example, we would exclude financing, sales tax, freight, installation and testing, excise taxes, legal or accounting fees, and maintenance. This specific price element would act as the proxy for the all-encompassing cost basis in other accounting methodologies. Using the straight-line depreciation method, we would divide the MAC-determined price by the useful life of the capital-related asset that is a home dialysis machine when used in the home for a single patient. The resulting number is the annual allowance.

We considered other depreciation methods, such as units of production and accelerated depreciation methods such as double declining balance and sum-of-the-years-digits, but concluded that these methods would be more complex to implement and that the simpler method would be preferable for the calculation of an add-on payment adjustment. In addition, we stated in the CY 2021 ESRD PPS proposed rule that since we are not reimbursing the cost of the equipment, nor are we revising the ESRD PPS at the end of the two-year add-on payment period, based on the information gathered, we believe this policy is appropriate for encouraging and supporting the uptake of new and innovative renal dialysis equipment and supplies.

In order to determine the basis of payment for capital-related assets that are home dialysis machines when used in the home for a single patient, we proposed certain additional steps that MACs would take after determining the price to develop the TPNIES per treatment payment amount. That is, we proposed to add paragraph (f) to § 413.236 to establish the pricing for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient that meet the eligibility criteria in § 413.236(b). We proposed in § 413.236(f)(1) that, using the price determined under § 413.236(e), the MACs would follow a 2-step methodology for calculating a pre-adjusted per treatment amount.

Under the first step, the MACs would determine the annual allowance that represents the amount of the MAC-determined price that is allocable to 1 year. To calculate the annual allowance, we proposed that the MACs would use the straight-line depreciation method by dividing the MAC-determined price by the useful life of the home dialysis machine. In accordance with the straight-line depreciation method, the MAC would divide the MAC-determined price by 5 (the useful life for dialysis machines established by the AHA is 5 years).

Under the second step, the MACs would calculate a pre-adjusted per treatment amount by dividing the annual allowance by the expected number of treatments to yield a pre-adjusted per treatment amount. That is, the MACs would establish a pre-adjusted per treatment amount by dividing the annual allowance by the number of treatments expected to be furnished in a year. For home dialysis machines that are expected to be used 3 times per week, the annual number of treatments is 156 (3 treatments/week × 52 weeks = 156 treatments/year). We noted, for purposes of calculating this TPNIES add-on payment adjustment, MACs do not determine the number of expected treatments. This information will be provided by CMS through the Change Request.

(a) Alternative To Offset the Pre-Adjusted Per Treatment Amount

In the CY 2011 ESRD PPS final rule (75 FR 49075), we stated that when we computed the ESRD PPS base rate, we used the composite rate payments made under Part B in 2007 for dialysis in computing the ESRD PPS base rate. These are identified in Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) as ''composite rate services.'' Sections 1881(b)(14)(A)(i) and 1881(b)(14)(B) of the Act specify the renal dialysis services that must be included in the ESRD PPS bundled payment, which includes items and services that were part of the composite rate for renal dialysis services as of December 31, 2010. As we indicated in the CY 2011 ESRD PPS proposed rule (74 FR 49928), the case-mix adjusted composite payment system represents a limited PPS for a bundle of outpatient renal dialysis services that includes maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies and staff time (74 FR 49928). In the CY 2011 ESRD PPS final rule (75 FR 49062), we noted that total composite rate costs in the per treatment calculation included costs incurred for training expenses, as well as all home dialysis costs.

In addition, as we discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42150 through 42151), these composite rate payments, and consequently the ESRD PPS base rate, include an amount associated with the costs of capital-related assets that are home dialysis machines. As we discussed in the CY 2021 ESRD PPS proposed rule, we believe that capital-related assets are distinguishable from drugs and biological products and supplies, which are single-use or disposable items, whereas ESRD facilities can continually use a home dialysis machine past its expected useful life and for multiple patients (consecutively). Therefore, we stated that an offset of the proposed TPNIES pre-adjusted per treatment amount may be warranted so that the TPNIES would cover the estimated marginal costs of new and innovative home dialysis machines. That is, ESRD facilities using the new and innovative

home dialysis machine would receive a per treatment payment to cover some of the cost of the new machine per treatment minus a per treatment payment amount that we estimate to be included in the ESRD PPS base rate for current home dialysis machines that they already own.

To account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own, we considered an alternative to our proposal that would include an additional step to calculating the TPNIES. That is, we would apply an offset to the pre-adjusted per treatment amount. We noted in the CY 2021 ESRD PPS proposed rule that if we were to adopt an offset in the final rule, we would add language to the proposed § 413.236(f) specifying the methodology used to compute the offset and its place—the final step—in the computation of the TPNIES for new and innovative home dialysis machines that meet the eligibility criteria.

(b) Methodology for Estimating Home Machine and Equipment Cost Per Home Treatment

In order to establish the value of the offset, which would be an estimate of an average home dialysis machine and equipment cost per HD-equivalent home dialysis treatment to use as the offset amount, we proposed the following methodology. First, we would estimate annualized dialysis machine and equipment cost and treatment counts from cost reports for each ESRD facility for 2018. Next, we would compute an HD-equivalent home dialysis treatment percentage for each ESRD facility by dividing the annualized HD-equivalent home treatment counts by the annualized HD-equivalent treatment counts across all modalities. Then we would apply the home dialysis treatment percentage to the annualized dialysis machine and equipment cost to derive an estimated home dialysis machine and equipment cost for each ESRD facility. Next, we would aggregate the home dialysis machine and equipment costs and the HD-equivalent home treatment counts to derive an average home dialysis machine and equipment cost per home dialysis treatment across all ESRD facilities. Finally, we would inflate the 2018 average home dialysis machine and equipment cost per home treatment to 2021 using the ESRDB market basket update less productivity for CY 2019, CY 2020, and CY 2021, and scale the costs to ESRD PPS payments using the ratio of total cost per treatment for CY 2021, which is obtained by scaling the CY 2018 cost per treatment to CY 2021 using the ESRDB market basket update less productivity for CY 2019, CY 2020, and CY 2021, to the total ESRD PPS payment per treatment projected for CY 2021.

We would obtain annualized dialysis machine and equipment cost and treatment counts from freestanding and hospital-based ESRD cost reports. For independent/freestanding ESRD facilities, we would use renal facility cost reports (CMS form 265–11). We would obtain dialysis machine and equipment cost [12] from Worksheet B, Column 4, and sum up Lines 8.01 through 17.02. We would obtain dialysis treatment counts by modality from Worksheet D, Column 1, Lines 1 through 10. Since home continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) treatment counts are reported in patient weeks, we would multiply them by 3 to get HD-equivalent counts. Finally, we would aggregate all home dialysis treatment counts to obtain each ESRD facility's HD-equivalent home dialysis treatment counts and we would aggregate the treatment counts to obtain each freestanding ESRD facility's HD-equivalent dialysis treatment counts for all modalities.

For hospital-based ESRD facilities, we would use hospital cost reports (CMS form 2552–10). We would obtain dialysis machine and equipment cost from Worksheet I–2, Column 2, and then sum up Lines 2 through 11. We would derive dialysis treatment counts by modality from Worksheet I–4, Column 1, Lines 1 through 10. Home Continuous Ambulatory Peritoneal Dialysis and Continuous Cyclic Peritoneal Dialysis treatment counts are reported in patient weeks, so we would multiply them by 3 to get HD-equivalent counts. We would aggregate all home treatment counts to obtain each hospital-based ESRD facility's HD-equivalent home dialysis treatment counts. Then we would aggregate all treatment counts to obtain each hospital-based ESRD facility's HD-equivalent dialysis treatment counts for all modalities.

We stated in the CY 2021 ESRD PPS proposed rule that using this methodology for both freestanding and hospital-based ESRD facilities would result in an offset of $9.23. We noted that if we were to adopt this approach, the MAC would apply this additional step in calculating the pre-adjusted per treatment amount. That is, the MAC would offset the pre-adjusted per treatment amount by deducting $9.23 to account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own. We stated that we believe this methodology would provide an approximation of the cost of the home dialysis machine in the base rate. Further, we noted that we believe deducting this amount from the calculated pre-adjusted per treatment amount would be reasonable because the beneficiary would not be using two home dialysis machines at the same time and at the end of the 2 years, the ESRD facility would retain ownership of the asset, specifically, the home dialysis machine.

We solicited comments on this alternative approach to apply an offset to the proposed pre-adjusted per treatment amount and specifically solicited comments on the methodology we would use to compute the value of the offset.

Finally, consistent with the policies finalized last year in § 413.236(d) for the TPNIES, we proposed to revise § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount for capital-related assets that are home dialysis machines when used in the home for a single patient. That is, as discussed in the CY 2020 ESRD PPS final rule (84 FR 60692 through 60693), we finalized a policy to base the TPNIES payment on 65 percent of the MAC-determined price in order to maintain consistency with the IPPS NTAP payment policy and to mitigate the Medicare expenditures incurred as a result of the TPNIES. Therefore, we proposed to pay 65 percent of the pre-adjusted per treatment amount for these machines.

For example, for a home dialysis machine that has a MAC-determined price of $25,000 and a 5-year useful life, using the proposed straight-line depreciation method, the annual allowance would equate to $5,000 per year. At 156 treatments per year, the pre-adjusted per treatment amount is $32.05 ($5,000/156) and 65 percent of that amount equals a TPNIES per treatment add-on payment amount of $20.83 ($32.05 × .65). We noted that, currently, the useful life of 5 years and the expected number of treatments of 156 is fixed since these variables have been established by CMS. That is, as we discussed previously in this section with regard to the use of the AHA

[12] Here dialysis machine and equipment cost includes capital-related costs of moveable equipment, rented and/or purchased, and maintenance on the dialysis machine and any support equipment. This also includes the equipment and associated maintenance and repair and installation costs necessary to render the water acceptable for use in dialysis.

guidance that dialysis machines have a 5-year useful life. With regard to the expected number of treatments, this is based on the current payment policy of 3 treatments per week. Under the alternative proposal, we would reduce the pre-adjusted per treatment add-on payment amount ($32.05) by $9.23 to offset the amount for a dialysis machine included in the base rate ($32.05 − $9.23 = $22.82). Then 65 percent of that amount would equal a TPNIES per treatment add-on payment amount of $14.83 ($22.82 × .65).

We explained in the CY 2021 ESRD PPS proposed rule that in the future, if an innovative home dialysis machine is designed to require fewer treatments per week relative to existing machines, MACs, using the same methodology could account for fewer treatments in the denominator in the calculation of the pre-adjusted per treatment amount. This change to the denominator would allow the total TPNIES amount paid at the end of the year to be equivalent to the annual allowance and we would then proceed with the calculation to achieve the targeted 65 percent of that annual allowance.

For a PD cycler that is used 7 times per week, the annual allowance for TPNIES would remain at $5,000 per year. A daily modality, or 7 treatments per week, equals 364 treatments per year (7 treatments per week × 52 weeks = 364 treatments per year). The annual allowance (numerator) would be divided by the number of treatments (denominator). At 364 treatments per year, the pre-adjusted per treatment amount would be $13.74 ($5,000/364 treatments = $13.74); and 65 percent of that amount would yield a TPNIES per treatment add-on payment of $8.93. Under the alternative proposal, we would reduce the pre-adjusted per treatment add-on payment amount ($13.74) by an offset to reflect the amount for a dialysis machine included in the base rate. We would apply the HD-equivalency calculation, that is used to convert PD treatments for payment purposes, to the offset since the per treatment amount in this example is a daily modality. Therefore, the offset would be $3.96 ($9.23*(3/7) = $27.69/7 = $3.96). Then the pre-adjusted per treatment add-on payment amount would be $9.51 ($13.47 − $3.96 = $9.51). Then 65 percent of that amount would equal a TPNIES per treatment add-on payment amount of $6.18 ($9.51 × .65 = $6.18).

The methodology is the same. The two variables, regardless of modality, are: (1) The cost of the machine used to calculate annual allowance (2) the number of treatments the machine is expected to deliver per year.

We invited public comment on using the proposed and alternative method for determining the pricing of capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the eligibility criteria in § 413.236(b), including the revisions discussed in section II.B.3.b.(1) of this final rule.

Consistent with the TPNIES policy and in accordance with § 413.236(d)(1), we proposed that we would apply the TPNIES for these home dialysis machines for 2-calendar years from the effective date of the change request, which would coincide with the effective date of a future CY ESRD PPS final rule. In the change request we would specify that the add-on payment adjustment would be applicable to home dialysis treatments and provide the billing guidance on how to report the miscellaneous code for the eligible item on the claim until a permanent HCPCS is available.

As we stated in the CY 2021 ESRD PPS proposed rule, we believe the duration of the application of the TPNIES for all equipment and supplies determined eligible for this payment adjustment should be consistent, and that 2 years would be a sufficient timeframe for ESRD facilities to set up or adjust business practices so that there is seamless access to the new and innovative home dialysis machines. In addition, we noted that in light of the current COVID–19 pandemic, stakeholders are increasingly aware of the importance of having home dialysis readily available and in place to prevent ESRD patients from being exposed to asymptomatic or pre-symptomatic infections that contribute to COVID–19 transmission by having to utilize in-center dialysis.

We further stated that we believe that providing the TPNIES for 2 years for these machines would address the stakeholders' concerns regarding additional payment to account for higher cost of more new and innovative home dialysis machines that they believe may not be adequately captured by the dollars allocated in the ESRD PPS base rate. That is, we believe that the TPNIES would help remove barriers to market penetration and foster competition with other dialysis machines that are already on the market. In the CY 2021 ESRD PPS proposed rule, we noted that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary co-insurance, since we have not previously provided a payment adjustment for any capital-related assets in the past. However, to support HHS's goals and initiatives to increase home dialysis and the President's Executive order of July 10, 2019, we stated that we believe that the proposed expansion of the TPNIES to capital-related assets that are home dialysis machines when used in the home for a single patient would be appropriate to support ESRD facility uptake in furnishing new and innovative renal dialysis equipment to ESRD patients.

We noted that the intent of the proposed TPNIES for new and innovative capital-related assets that are home dialysis machines when used in the home would be to provide a transition period to support ESRD facility use of these machines when they are new and innovative to the market. We stated that, at this time, we do not believe that it would be appropriate to add dollars to the ESRD PPS base rate for new and innovative home dialysis machines because, as noted previously, the ESRD PPS base rate includes the cost of equipment and supplies used to furnish a dialysis treatment.

While we would monitor renal dialysis service utilization trends during the TPNIES payment period, we proposed that these capital-related assets that are home dialysis machines when used in the home would not be eligible outlier services as provided in § 413.237. As assets, capital-related home dialysis machines are distinct from operating expenses such as the disposable supplies and leased equipment with no conveyed ownership rights. These expenses are generally accounted for on a per patient basis and therefore, when used in excess of the average constitute outlier use, which makes them eligible for outlier payments.

Therefore, we proposed revisions at § 413.236(d)(2) to reflect that following payment of the TPNIES for new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient, the ESRD PPS base rate will not be modified and the equipment would not be an eligible outlier service as provided in § 413.237. In addition, we proposed revisions at § 413.237(a)(1)(v) to exclude capital-related assets that are home dialysis machines when used in the home for a single patient from outlier eligibility after the TPNIES period ends. We also proposed minor editorial changes to paragraph (a)(1)(i) to remove the semicolon at the end of the sentence and add a period in its place; and in paragraph (a)(1)(iv) to remove ''; and'' and add a period in its place.

With regard to the TPNIES application, we would post any final

changes to both the timing of the various eligibility criteria and the content of the TPNIES application to the TPNIES website, along with information about all renal dialysis equipment and supplies that CMS has determined are eligible for the TPNIES, consistent with the policies we finalize in the CY 2021 ESRD PPS final rule. The TPNIES website is available at: *https://www.cms.gov/medicare/esrd-pps/esrd-pps-transitional-add-payment-adjustment-new-and-innovative-equipment-and-supplies-tpnies.*

The comments we received and our responses to the comments on our proposed and alternative pricing methodology are set forth below:

Comment: A group of organizations, representing the kidney and medical technology communities recommended that CMS extend the TPNIES period from 2 years to at least 3 years. They stated that 2 years is an inadequate amount of time after taking into account the scale of resources and time necessary to build a responsible support and distribution infrastructure nationwide. This is especially true for companies in their earlier stages, for example, small manufacturers that tend to lack the type of distribution and support infrastructure that their larger, more established counterparts may feature. Furthermore, staffing constraints could mean the technology would take too long to come to market, causing the ESRD facility to be unable to get the TPNIES for 2 years. Accordingly, the commenter stated that a 2-year TPNIES period creates a level of risk that would discourage smaller start-up companies from pursuing the development of new and innovative equipment and supplies. These commenters stated that extending the TPNIES period would help level the playing field between small innovators and large, global manufacturers with an existing support and distribution footprint. They pointed out that the new technology add-on payment that applies under the hospital inpatient setting allows for technologies to qualify for the add-on payment up to three years to account for the lag time in data collection to be reflected in updated MS–DRGs. Given that it takes significantly longer for devices, particularly home dialysis machines, to achieve significant adoption, they stated that CMS should align with the hospital inpatient policy and allow for an additional year of TPNIES.

Many commenters urged CMS to reconsider the proposed policy to limit the TPNIES to only 2 years and not adjust the base rate when truly innovative renal equipment and supplies are added to the ESRD PPS bundled payment. They noted that, experience with the TDAPA for calcimimetics demonstrates that having a three-year transition period is important for data collection purposes, giving CMS adequate time to review claims and determine whether the base rate should be adjusted. Commenters reported that small, independent and low-volume ESRD facilities continue to experience low to negative Medicare margins and that, while TDAPA and TPNIES can provide helpful transitional add-on payment adjustments for limited periods of time, they do not account for incorporating innovative renal drugs, equipment and supplies into high-quality clinical care over the long term. Commenters suggested that CMS could increase the base rate by the difference between the cost of the TPNIES-eligible device and the amount to dollars already in the base rate for similar devices and that this methodology would recognize the dollars already in the base rate, but still establish a fair, yet competitive, playing field allowing for long-term stability.

Other commenters pointed out that if a new home dialysis machine is eligible for the TPNIES in 2022 and 2023, only a machine that is used continuously between January 2022 and December 2023 will be reimbursed at an amount equivalent to 26 percent of the MAC-determined price. In contrast, a machine that is used continuously between January 2023 and December 2023 will be reimbursed at an amount equivalent to only 13 percent of the MAC-determined price. The commenter encouraged CMS to consider the following adaptation: If a home dialysis machine is eligible for the TPNIES in 2022 and 2023, then an ESRD facility may collect TPNIES payments for two years after the first use of the machine among all patients in the facility. In other words, an ESRD facility that collects its first TPNIES payment for a home dialysis machine in October 2022 will be eligible for continued payments through September 2024. Nevertheless, that ESRD facility must collect its first TPNIES payment no later than December 2023. The commenter stated that this adaptation would allow all ESRD facilities to have an opportunity to collect 26 percent of the MAC-determined price.

Response: We believe the commenter is requesting that we pay the TPNIES for 3 years, similar to the length of time we paid the TDAPA for calcimimetics, and that like calcimimetics we then adjust the base rate to account for the cost of such products. Since we are not adjusting the base rate for the equipment and supplies eligible for the TPNIES, the collection of data for a 3-year period of time is not necessary. We believe the payment of the TPNIES for 2 years is adequate time for ESRD facilities to incorporate new products into their business model. With regard to the commenters' concern with the duration of the TPNIES and when it would begin for ESRD facilities that are unable to obtain and report the equipment or supply on the claim beginning January 1, we understand the commenters' concern and will consider refinements to the TPNIES to address this issue in future rulemaking. We continue to believe that 2 years is adequate since the purpose of TPNIES is to support facility uptake of these items and that this policy strikes an appropriate balance between supporting ESRD facilities and limiting the financial burden that increased payments place on beneficiaries and Medicare expenditures. In addition, we note that this is the first year of implementing the TPNIES for capital related assets that are home dialysis machines and we intend to monitor the use and payments for the TPNIES to assess whether new and innovative machines are adopted by the ESRD facilities.

With regard to small manufacturers that may take longer to have their equipment or supply come to market, we note that the purpose of the TPNIES is to facilitate ESRD facility uptake of the new and innovative equipment and supplies. Unlike the IPPS NTAP that will end in an adjustment to the MS–DRG, there will be no change in the ESRD PPS base rate when TPNIES ends, therefore, the data collection needs are not the same. We believe providing 2 years of an add-on payment adjustment for supplies and equipment is sufficient time for market uptake if the manufacturers prepare in advance of the TPNIES application. Doing so will allow ESRD facilities to align their business plan to obtain 2 full years of TPNIES payments.

Comment: A commenter expressed concern that home dialysis machines were being defined as in their entirety, meaning that one new part of a machine does not make the entire capital-related asset new. The commenter explained that PD patients often have issues related to handling and storage of PD solution and if an innovator develops a machine that generates PD solution that interfaces with an existing cycler, the machine could not be considered for TPNIES eligibility. The commenter recommended that CMS finalize a TPNIES expansion that will offer a clear pathway to approval of machines that

produce on-demand PD solution. The commenter also questioned the disqualification of water purification systems, but recognized that the application of such systems to the home setting is unclear.

Response: The commenter is correct that a piece of equipment that is used along with a PD cycler or HD machine would not meet our definition of a home dialysis machine, however, such equipment could be considered for the TPNIES as renal dialysis equipment (which was finalized in the CY 2020 ESRD PPS final rule (84 FR 60691 through 60692) and implemented January 1, 2020). We note that the exclusion of other capital-related assets, such as water purification systems, applies to the systems used in ESRD facilities for in-center dialysis and benefits all in-center patients. Our payment methodology for capital-related assets that are home dialysis machines addresses individual patient use in the home and is not geared to assets that benefit all patients.

Comment: A group of organizations representing the kidney and medical technology communities requested that CMS instruct MACs to provide public, timely, and consistent payment determinations. They recommended that CMS exclude the language in the regulation that gives MACs flexibility to determine the pricing of any TPNIES supply, equipment or capital-related asset that meets the TPNIES eligibility criteria based on charges and payment amounts for other equipment and supplies that may be comparable or otherwise relevant. They stated that the regulatory language undermines CMS approvals for applicants of the TPNIES as, by definition, approved products have achieved SCI over existing products. They also recommended that CMS more clearly define the payment parameters and instruct the MACs to publish a database online that provides a discrete TPNIES payment amount no later than March 31 of the first year of TPNIES eligibility.

MedPAC supported the proposal to base the TPNIES amount on the price established by the MACs (using information from invoices and other relevant sources of information) but only for the first two calendar quarters after CMS begins applying the TPNIES. Thereafter, they recommended that CMS set the price of new equipment and supplies using a method based on pricing data collected directly from each manufacturer, similar to how the agency establishes the ASP for Part B drugs. They explained that the ASP for a Part B drug reflects the average price realized by the manufacturer for its sales broadly across different types of purchasers, for patients with different types of insurance coverage, and based on the manufacturer's sales to all purchasers (with certain exceptions) net of manufacturer rebates, discounts, and price concessions. They stated that an approach similar to how CMS collects ASP data would increase the consistency of pricing data and should lead to more accurate payment rates for items paid under the TPNIES. They further recommended that CMS link payment of the TPNIES to a requirement that equipment and supply manufacturers submit ASP-like data to the agency, similar to the TDAPA policy.

Response: We continue to believe that the payment amounts for other equipment and supplies that may be comparable or otherwise relevant, as described at § 413.236(e)(1)(iv) of this final rule, as an important consideration for the MACs to determine the price of any TPNIES supply, equipment or capital-related asset that meets the TPNIES eligibility criteria. While we recognize that TPNIES items will have demonstrated SCI over existing items, we seek to avoid Medicare paying 65 percent of an excessively inflated price, for example, a dialysis machine that is 3 times the cost of current machines. Since the manufacturer will determine the price to be paid by the provider, the MACs' consideration of charges and payment for comparable equipment and supplies serves as a guard rail for the use of invoice pricing. With regard to the suggestion that we instruct the MACs to publish an online database with TPNIES payment amounts, we are working with MACs on mechanisms for pricing transparency. We will consider the suggestion for future rulemaking. With regard to the suggestion for an ASP-like reporting system, we think the idea has merit and will take it into consideration for future rulemaking.

Comment: An organization of LDOs stated they are supportive of CMS fixing the expected number of treatments at 156 for the purpose of calculating the TPNIES value, however, they expressed significant concerns about any policy changes that would undermine the ability of treating physicians to prescribe the frequency of dialysis that is clinically appropriate for their patients. They suggested that CMS may be interested in capping the TPNIES payment for a device. They proposed that CMS adopt a modification to the methodology that would respect both the TPNIES cap and the importance of physician prescribing with regard to frequency of dialysis. For example, CMS could cap total TPNIES payments for a specific device at the maximum allowable TPNIES payment pursuant to the adopted methodology, even if that amount is achieved prior to the end of the 2-year TPNIES period.

Response: The purpose of the 156 treatments is to compute a per treatment amount. An ESRD patient's nephrologist may order additional reasonable and necessary dialysis treatments beyond 3 per week. When a MAC has determined that the additional treatments are reasonable and necessary, we would pay the TPNIES on each covered treatment that is furnished. At this time, we do not believe it is necessary to adopt the commenter's suggested modification to the proposed methodology that takes into account both the TPNIES cap and the prescribed frequency of dialysis; however, we will monitor use of the TPNIES and consider if such a policy is necessary for future rulemaking.

Comment: A group of organizations, representing the kidney and medical technology communities recommended that we establish a formal appeals process for the manufacturers whose applications for the TPNIES are denied. They expressed concern that, without an opportunity to review CMS' initial determination, situations may arise in which new technologies fail to obtain a favorable TPNIES determination due to technical errors or insufficient information necessary in the initial TPNIES application. They asserted that a formal appeals process would ensure that TPNIES applicants would have an opportunity to seek additional, independent review as necessary. They noted that the standard process for seeking review of Medicare Part A/B claims under 42 CFR part 405, subpart I, may not apply, and encouraged CMS to allow for administrative appeals of TPNIES determinations to be conducted within the Office of Medicare Hearings and Appeals (that is, a hearing before the Departmental Appeals Board).

Response: We did not propose a formal appeals process for the manufacturers whose applications for TPNIES are denied for CY 2021 and therefore we are not adopting the suggestion. However, we thank the commenters for this suggestion and will consider it for future rulemaking. We note that applicants may reapply for the TPNIES if their application is denied as long as they reapply within 3 years of the date of FDA marketing authorization or approval.

Comment: A commenter expressed confusion about the discussion in the proposed rule on treatment frequency insofar as it is determinative of TPNIES payment. The commenter stated that, while the discussion is easier to

contemplate for PD, as most patients undergo treatment 6 or 7 days per week, it does not make sense for HD. The commenter noted that HD prescriptions can be written for as few as 2 days or as many as 7 days per week, and there is no concept of an ''ordinary'' treatment frequency for a HD machine, whether it is used in a facility or at home. The commenter recommended that CMS simply issue a TPNIES payment on a monthly basis according to whether the ESRD facility claim includes a condition code that indicates that a qualifying home dialysis machine has been used.

Response: We disagree with the commenter's assertion that there is no ordinary treatment frequency for HD machines. In-center HD machines are designed to be used 3 times per week to achieve adequate dialysis. Our intention of providing examples in the CY 2021 ESRD PPS proposed rule using various annual treatments was to clarify that the methodology for calculating the TPNIES per treatment payment can also be used if a new home dialysis machine was designed to achieve adequate dialysis in fewer treatments per week. We note that, when questioned specifically about frequency, a home dialysis machine manufacturer confirmed that adequate dialysis can be achieved in 3 treatments per week, however, the treatments may take longer to administer.

Comment: An LDO recommended that we set the useful life for home dialysis machines at 7 years rather than the 5 years we proposed. The organization noted that standard accounting practice is to depreciate dialysis equipment, for the center or the home, over a period of at least 7 years.

Response: Medicare policies [13] hold providers to strict AHA guidelines with respect to the useful life. Under AHA guidelines, useful life for dialysis machines is 5 years. ESRD facilities are allowed to use more or less than the AHA guidelines for business financial reporting but they must use the AHA guidelines for Medicare.

Comment: MedPAC did not support expanding the TPNIES to include home dialysis equipment, but stated that, if CMS finalizes its proposal, it should remove the portion of payment attributable to home dialysis machines from the base rate for those cases receiving the TPNIES because paying for new home dialysis machines under the TPNIES for two years is duplicative of payment for items with a similar purpose or use that are already paid under the ESRD PPS base rate. MedPAC stated that it supported the proposal if CMS subtracted the amount for capital-related machines already included in the ESRD PPS base rate for those cases receiving the TPNIES.

While some commenters expressed support for the offset, an organization of renal professionals, providers and manufacturers, an organization of LDOs, and an individual objected to offsetting the TPNIES with the cost of the home dialysis machine already included in the base rate, stating that the purpose of a transitional add-on payment is to incentivize the adoption of innovative products. These commenters stated that the purpose of the TPNIES is not to reimburse providers dollar for dollar for their costs. In their view, the government assumes the risk of making an additional payment during the TPNIES period with the presumed reward of beneficiaries experiencing clinical improvement, as claimed by the applicant. Following the end of the TPNIES period, the providers assume that risk. The commenters asserted that this is true of the inpatient and outpatient hospital payment systems, as well as the TPNIES. They stated, given that the proposed TPNIES amount is only a portion of the cost providers incur when using the device, further reducing the TPNIES amount with the offset would only further reduce the likelihood of adoption of the machine.

Response: We agree with MedPAC that the TPNIES payment is duplicative of payment for items with a similar purpose or use that are already paid under the ESRD PPS base rate. For this reason, we are finalizing an offset to the TPNIES payment, which we discussed in the CY 2021 ESRD PPS rule, to reflect the value of the dialysis machine included in the ESRD PPS base rate.

We disagree with the commenters who stated that applying an offset to reflect the amount for a dialysis machine in the base rate would reduce the likelihood the new machine will be purchased by ESRD facilities. We believe that ESRD facilities will need to buy additional dialysis machines to support the goals of the Executive order and the ETC model and that the TPNIES payment will help support ESRD facility uptake of new home dialysis machines.

Final Rule Action: After careful consideration of the comments we received, we are finalizing our proposed pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient and the proposed changes to § 413.236(f) requiring MACs to calculate the annual allowance and the pre-adjusted per treatment amount with revisions.

Since we are finalizing an offset to the TPNIES payment to reflect the value of a dialysis machine in the ESRD PPS base rate, we revised the proposed changes to § 413.236(f) to reflect the additional step of calculating a per treatment amount for use in calculating the pre-adjusted per treatment amount. We also revised paragraph (f) to reflect that the pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate.

In the CY 2021 ESRD PPS proposed rule, we stated our intention to further amend § 413.236(f) if we finalized the offset. Since we are finalizing the offset, we are adding the data sources and methodological steps for computing the offset in paragraph (f). In the proposed rule the $9.23 offset was based on the proposed CY 2021 ESRDB market basket less the multifactor productivity adjustment. For this final rule, we have recomputed the offset to reflect the final CY 2021 payment rate update factor (1.6 percent). The final offset for CY 2021 is $9.32. We will continue to update the offset amount on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

We are also finalizing the revision to § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines when used in the home for a single patient.

4. CY 2021 ESRD PPS Update

a. CY 2021 ESRD Bundled (ESRDB) Market Basket Update, Productivity Adjustment, and Labor-Related Share

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD

[13] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

Bundled (ESRDB) input price index (75 FR 49151 through 49162). In the CY 2015 ESRD PPS final rule we rebased and revised the ESRDB input price index to reflect a 2012 base year (79 FR 66129 through 66136). Subsequently, in the CY 2019 ESRD PPS final rule, we finalized a rebased ESRDB input price index to reflect a 2016 base year (83 FR 56951 through 56962).

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

We proposed to use the CY 2016-based ESRDB market basket as finalized and described in the CY 2019 ESRD PPS final rule (83 FR 56951 through 56962) to compute the CY 2021 ESRDB market basket increase factor based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket update based on IHS Global Inc.'s (IGI's), forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. Using this methodology and IGI's first quarter 2020 forecast of the CY 2016-based ESRDB market basket (with historical data through the fourth quarter of 2019), the proposed CY 2021 ESRDB market basket increase factor was 2.2 percent.

Under section 1881(b)(14)(F)(i) of the Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The growth in multifactor productivity (MFP) is derived by subtracting the contribution of labor and capital input growth from output growth. We finalized the detailed methodology for deriving the MFP projection in the CY 2012 ESRD PPS final rule (76 FR 40503 through 40504). The most up-to-date MFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/MFPMethodology.pdf.* Using this methodology and IGI's first quarter 2020 forecast, the proposed MFP adjustment for CY 2021 (the 10-year moving average of MFP for the period ending CY 2021) was projected to be 0.4 percent.

As a result of these provisions, the proposed CY 2021 ESRD market basket adjusted for MFP was 1.8 percent. The proposed market basket increase is calculated by starting with the proposed CY 2021 ESRDB market basket percentage increase factor of 2.2 percent and reducing it by the proposed MFP adjustment (the 10-year moving average of MFP for the period ending CY 2021) of 0.4 percentage point. We also proposed that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket update or MFP), we would use such data, if appropriate, to determine the final CY 2021 market basket update and/or MFP adjustment (85 FR 42152).

The comments and our responses to the comments on the proposed ESRD market basket update and MFP adjustment for CY 2021 are set forth below.

Comment: Several commenters stated that with new drugs being added to the ESRD PPS bundled payment, it is more important than ever to use the most appropriate price proxies for determining the base rate and update each year. The commenters urged the adoption of a better price proxy for non-ESAs that are not over-the-counter (OTC) vitamins and recommended that CMS use the BLS Series ID: WPS063 Series Title: PPI Commodity Data for Chemicals and Allied Products-Drugs and Pharmaceuticals, seasonally adjusted. One commenter stated that the timing of addressing the price proxy used for non-ESA drugs in the ESRD market basket is relevant since new drugs in the pipeline could be added to the ESRD PPS bundled payment during the next few years because of the TDAPA provisions.

Response: We appreciate the commenters' suggestion that we use the most appropriate price proxy for non-ESA drugs in the ESRD market basket. We did not propose changes to the price proxies in the ESRD market basket for CY 2021, so we will not be adopting such changes in this final rule. However, as described in the CY 2019 ESRD PPS final rule (83 FR 56960 through 56961), we believe the PPI for Vitamins, Nutrients, and Hematinic Preparation (VNHP) is the most appropriate price proxy for non-ESA drugs and analysis of the ASP data for Non-ESA drugs in the bundle suggests the trends in the PPI VNHP trends are reasonable. We appreciate the commenters' concern for the potential shifts in the mix of drugs within the ESRD PPS bundled payment amount as a result of the TDAPA provisions. We will continue to monitor the impact that these changes have on the relative cost share weights and the mix of non-ESA drugs included in the bundled payment in the ESRDB market basket.

Comment: One commenter expressed support for the annual update to the ESRD PPS base rate for CY 2021 and recognized that CMS does not have the authority to eliminate the productivity adjustment, but wanted to highlight their continued concern about the overall negative Medicare margins. The commenter stated that the experience of ESRD facilities disputes the idea that productivity in ESRD facilities can be improved year over year at the rate of economy-wide productivity.

Response: Section 1881(b)(14)(F)(i) of the Act requires the application of the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the ESRD PPS market basket update for 2012 and subsequent years. We will continue to monitor the impact of the payment updates, including the effects of the MFP adjustment, on ESRD provider margins as well as beneficiary access to care as reported by MedPAC. However, any changes to the productivity adjustment would require a change to current law.

In the March 2020 Report to Congress, MedPAC found most indicators of payment adequacy to be positive, and recommend that for 2021, the ESRD PPS base rate should be updated by the amount determined under current law.

Final Rule Action: Consistent with our historical practice and our proposal, we are estimating the market basket increase and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's third quarter 2020 forecast with historical data through the second quarter of 2020, the 2016-based ESRDB market basket percentage increase for CY 2021 is 1.9 percent. We note that the first quarter 2020 forecast used for the proposed market basket update was developed prior to the economic impacts of the COVID–19 pandemic. This lower update (1.9 percent) for CY 2021 relative to the CY 2021 ESRD PPS proposed rule (2.2 percent) is primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets are expected to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery.

Based on the more recent data available for this CY 2021 ESRD PPS final rule, the current estimate of the 10-year moving average growth of MFP for CY 2021 is projected to be 0.3 percent.

This MFP estimate is based on the most recent macroeconomic outlook from IGI at the time of rulemaking (released September 2020) in order to reflect more current historical economic data. IGI produces monthly macroeconomic forecasts, which include projections of all of the economic series used to derive MFP. In contrast, IGI only produces forecasts of the more detailed price proxies used in the 2016-based ESRDB market basket on a quarterly basis. Therefore, IGI's third quarter 2020 forecast is the most recent forecast of the 2016-based ESRD market basket percentage increase factor.

We note that it has typically been our practice to base the projection of the market basket price proxies and MFP in the final rule on the third quarter IGI forecast. For this CY 2021 ESRD PPS final rule, we are using the IGI September macroeconomic forecast for MFP because it is a more recent forecast, and it is important to use more recent data during this period when economic trends, particularly employment and labor productivity, are notably uncertain because of the COVID–19 pandemic. However, we also note that the 10-year moving average of MFP based on the third quarter 2020 forecast is also 0.3 percent.

Therefore, the final CY 2021 ESRD PPS payment rate update is 1.6 percent. That is, the CY 2021 ESRD market basket percentage increase factor of 1.9 percent less the 0.3 percentage point MFP adjustment (the 10-year moving average of MFP for the period ending CY 2021).

For the CY 2021 ESRD payment update, we proposed to continue using a labor-related share of 52.3 percent for the ESRD PPS payment, which was finalized in the CY 2019 ESRD PPS final rule (83 FR 56963). We did not receive any public comments on this proposal and therefore, we are finalizing the continued use of a 52.3 percent labor-related share for CY 2021.

b. The CY 2021 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget's (OMB's) core-based statistical area (CBSA)-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/.*

For CY 2021, we updated the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We used the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2021, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2016 and before October 1, 2017 (FY 2017 cost report data).

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA, that is, we use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We apply the statewide urban average based on the average of all urban areas within the state to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172). In the CY 2021 ESRD PPS proposed rule (85 FR 42152), we noted that for the CY 2020 ESRD PPS final rule, we did not apply the statewide urban average to Carson City, Nevada as we did in the CY 2020 ESRD PPS proposed rule (84 FR 38359) because hospital data was available to compute the wage index.

A wage index floor value (0.5000) is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor. A description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2019 ESRD PPS final rule (83 FR 56963), we finalized a labor-related share of 52.3 percent, which is based on the 2016-based ESRDB market basket. Thus, for CY 2021, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

For CY 2021, in addition to updating the ESRD PPS wage index to use more recent hospital wage data, we also proposed to adopt newer OMB delineations and a transition policy in a budget-neutral manner as discussed in the CY 2021 ESRD PPS proposed rule and sections II.B.4.b.(2) and II.B.4.b.(3), respectively, of this final rule.

(2) Implementation of 2018 OMB Labor Market Delineations

As discussed previously in the CY 2021 ESRD PPS proposed rule and this final rule, the wage index used for the ESRD PPS is calculated using the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS and is assigned to an ESRD facility on the basis of the labor market area in which the ESRD facility is geographically located. ESRD facility labor market areas are delineated based on the CBSAs established by the OMB. In accordance with our established methodology, we have historically adopted through rulemaking CBSA changes that are published in the latest OMB bulletin. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses.

In the CY 2015 ESRD PPS final rule (79 FR 66137 through 66142), we finalized changes to the ESRD PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01 [14] issued on February 28, 2013. We implemented these changes with a 2-year transition period (79 FR 66142). OMB Bulletin No. 13–01 established revised delineations for U.S. Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas based on the 2010 Census. OMB Bulletin No. 13–01 also provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252).

On July 15, 2015, OMB issued OMB Bulletin No. 15–01,[15] which updated and superseded OMB Bulletin No. 13–01 issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2012 and July 1, 2013.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01,[16] which updated and superseded OMB Bulletin No. 15–01 issued on July 15, 2015. The attachment to OMB Bulletin No. 17–01 provided detailed information on the update to statistical areas since July 15, 2015. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17–01, OMB announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 [17] which updated and superseded OMB Bulletin No. 17–01 issued on August 15, 2017. The attachment to OMB Bulletin No. 18–03 provided detailed information on the update to statistical areas since August 15, 2017. On September 14, 2018, OMB issued OMB Bulletin No. 18–04,[18] which updated and superseded OMB Bulletin No. 18–03 issued on April 10, 2018. OMB Bulletin Numbers 18–03 and 18–04 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2015 and July 1, 2016.

As we discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42153), while OMB Bulletin No. 18–04 is not based on new census data, there were some material changes to the CBSA-based geographic area designations based on the 2018 OMB delineations. For example, some new CBSAs and urban counties would become rural, rural counties would become urban, and existing CBSAs would be split apart. We explained that we believe that the 2018 OMB delineations accurately reflect the local economies and wage levels of the areas where ESRD facilities are located. We also explained that we believe it is important for the ESRD PPS to use the most recent OMB delineations practicable in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We further believe that using the newer OMB delineations would increase the integrity of the ESRD PPS wage index system by creating a more accurate representation of geographic variations in wage levels.

Therefore, we proposed to adopt the newer OMB delineations established in OMB Bulletin No. 18–04 effective for CY 2021 under the ESRD PPS. We also proposed a wage index transition applicable to all ESRD facilities that experience negative impacts due to the proposed implementation of the 2018 OMB delineations. This transition policy is discussed in section II.B.4.b.(3) of the CY 2021 ESRD PPS proposed rule and section II.B.4.b.(3) of this final rule.

In the CY 2021 ESRD PPS proposed rule (85 FR 42153), we noted that, on March 6, 2020, OMB issued OMB Bulletin 20–01 (available at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). While the March 6, 2020 OMB Bulletin 20–01 was not issued in time for development of the proposed rule, we were able to review the updates it provides and have determined that they were minor. We stated that while we do not believe the minor updates included in OMB Bulletin 20–01 would impact our CY 2021 updates to the CBSA-based labor market area delineations, if appropriate, we would propose any updates from this Bulletin in the CY 2022 ESRD PPS proposed rule.

As we stated in the CY 2021 ESRD PPS proposed rule (85 FR 42153), to implement the newer OMB delineations established in OMB Bulletin No. 18–04 under the ESRD PPS beginning in CY 2021, it is necessary to identify the new labor market area delineation for each affected county and ESRD facility in the U.S. We discuss these changes in more detail in the following sections.

(a) Urban Counties That Would Become Rural Under the 2018 OMB Delineations

In the CY 2021 ESRD PPS proposed rule (85 FR 42153 through 42155), we proposed to implement the 2018 OMB labor market area delineations (based upon the 2010 Decennial Census data) beginning in CY 2021. Our analysis of the 2018 OMB delineations showed that a total of 34 counties (and county equivalents) that are currently considered part of an urban CBSA would be considered located in a rural area, beginning in CY 2021. In the CY 2021 ESRD PPS proposed rule (85 FR 42154), we listed the 34 urban counties as set forth in Table 1, which would be rural if we finalized our proposal to adopt the 2018 OMB delineations beginning in CY 2021.

TABLE 1—CY 2021 PROPOSED URBAN TO RURAL CBSA CROSSWALK

FIPS county code	County/county equivalent	State	Current CBSA	CBSA title
01127	WALKER	AL	13820	Birmingham-Hoover, AL.
12045	GULF	FL	37460	Panama City, FL.
13007	BAKER	GA	10500	Albany, GA.

[14] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf.*

[15] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf.*

[16] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

[17] *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf.*

[18] *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*

TABLE 1—CY 2021 PROPOSED URBAN TO RURAL CBSA CROSSWALK—Continued

FIPS county code	County/county equivalent	State	Current CBSA	CBSA title
13235	PULASKI	GA	47580	Warner Robins, GA.
15005	KALAWAO	HI	27980	Kahului-Wailuku-Lahaina, HI.
17039	DE WITT	IL	14010	Bloomington, IL.
17053	FORD	IL	16580	Champaign-Urbana, IL.
18143	SCOTT	IN	31140	Louisville/Jefferson County, KY-IN.
18179	WELLS	IN	23060	Fort Wayne, IN.
19149	PLYMOUTH	IA	43580	Sioux City, IA-NE-SD.
20095	KINGMAN	KS	48620	Wichita, KS.
21223	TRIMBLE	KY	31140	Louisville/Jefferson County, KY-IN.
22119	WEBSTER	LA	43340	Shreveport-Bossier City, LA.
26015	BARRY	MI	24340	Grand Rapids-Wyoming, MI.
26159	VAN BUREN	MI	28020	Kalamazoo-Portage, MI.
27143	SIBLEY	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI.
28009	BENTON	MS	32820	Memphis, TN-MS-AR.
29119	MC DONALD	MO	22220	Fayetteville-Springdale-Rogers, AR-MO.
30037	GOLDEN VALLEY	MT	13740	Billings, MT.
31081	HAMILTON	NE	24260	Grand Island, NE.
38085	SIOUX	ND	13900	Bismarck, ND.
40079	LE FLORE	OK	22900	Fort Smith, AR-OK.
45087	UNION	SC	43900	Spartanburg, SC.
46033	CUSTER	SD	39660	Rapid City, SD.
47081	HICKMAN	TN	34980	Nashville-Davidson—Murfreesboro—Franklin, TN.
48007	ARANSAS	TX	18580	Corpus Christi, TX.
48221	HOOD	TX	23104	Fort Worth-Arlington, TX.
48351	NEWTON	TX	13140	Beaumont-Port Arthur, TX.
48425	SOMERVELL	TX	23104	Fort Worth-Arlington, TX.
51029	BUCKINGHAM	VA	16820	Charlottesville, VA.
51033	CAROLINE	VA	40060	Richmond, VA.
51063	FLOYD	VA	13980	Blacksburg-Christiansburg-Radford, VA.
53013	COLUMBIA	WA	47460	Walla Walla, WA.
53051	PEND OREILLE	WA	44060	Spokane-Spokane Valley, WA.

We proposed that the wage data for all ESRD facilities located in the counties listed above would be considered rural, beginning in CY 2021, when calculating their respective state's rural wage index. We stated in the CY 2021 ESRD PPS proposed rule (85 FR 42155) that we recognize that rural areas typically have lower area wage index values than urban areas, and ESRD facilities located in these counties may experience a negative impact in their payment under the ESRD PPS due to the proposed adoption of the 2018 OMB delineations. A discussion of the proposed wage index transition policy is available in section II.B.4.b.(3) of the CY 2021 ESRD PPS proposed rule and section II.B.4.b.(3) of this final rule.

(b) Rural Counties That Would Become Urban Under the 2018 OMB Delineations

In the CY 2021 ESRD PPS proposed rule (85 FR 42155 through 42157), we proposed to implement the 2018 OMB labor market area delineations (based upon the 2010 Decennial Census data) beginning in CY 2021. Our analysis of the 2018 OMB delineations showed that a total of 47 counties (and county equivalents) that are currently considered located in rural areas would be considered located in urban CBSAs, beginning in CY 2021. In the CY 2021 ESRD PPS proposed rule (85 FR 42156), we listed the 47 rural counties that would be urban, as set forth in Table 2, if we finalized our proposal to adopt the 2018 OMB delineations beginning in CY 2021.

TABLE 2—CY 2021 PROPOSED RURAL TO URBAN CBSA CROSSWALK

FIPS county code	County/county equivalent	State name	Proposed CBSA	Proposed CBSA title
01063	GREENE	AL	46220	Tuscaloosa, AL.
01129	WASHINGTON	AL	33660	Mobile, AL.
05047	FRANKLIN	AR	22900	Fort Smith, AR-OK.
12075	LEVY	FL	23540	Gainesville, FL.
13259	STEWART	GA	17980	Columbus, GA-AL.
13263	TALBOT	GA	17980	Columbus, GA-AL.
16077	POWER	ID	38540	Pocatello, ID.
17057	FULTON	IL	37900	Peoria, IL.
17087	JOHNSON	IL	16060	Carbondale-Marion, IL.
18047	FRANKLIN	IN	17140	Cincinnati, OH-KY-IN.
18121	PARKE	IN	45460	Terre Haute, IN.
18171	WARREN	IN	29200	Lafayette-West Lafayette, IN.
19015	BOONE	IA	11180	Ames, IA.
19099	JASPER	IA	19780	Des Moines-West Des Moines, IA.
20061	GEARY	KS	31740	Manhattan, KS.
21043	CARTER	KY	26580	Huntington-Ashland, WV-KY-OH.

TABLE 2—CY 2021 PROPOSED RURAL TO URBAN CBSA CROSSWALK—Continued

FIPS county code	County/county equivalent	State name	Proposed CBSA	Proposed CBSA title
22007	ASSUMPTION	LA	12940	Baton Rouge, LA.
22067	MOREHOUSE	LA	33740	Monroe, LA.
25011	FRANKLIN	MA	44140	Springfield, MA.
26067	IONIA	MI	24340	Grand Rapids-Kentwood, MI.
26155	SHIAWASSEE	MI	29620	Lansing-East Lansing, MI.
27075	LAKE	MN	20260	Duluth, MN-WI.
28031	COVINGTON	MS	25620	Hattiesburg, MS.
28051	HOLMES	MS	27140	Jackson, MS.
28131	STONE	MS	25060	Gulfport-Biloxi, MS.
29053	COOPER	MO	17860	Columbia, MO.
29089	HOWARD	MO	17860	Columbia, MO.
30095	STILLWATER	MT	13740	Billings, MT.
37007	ANSON	NC	16740	Charlotte-Concord-Gastonia, NC-SC.
37029	CAMDEN	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC.
37077	GRANVILLE	NC	20500	Durham-Chapel Hill, NC.
37085	HARNETT	NC	22180	Fayetteville, NC.
39123	OTTAWA	OH	45780	Toledo, OH.
45027	CLARENDON	SC	44940	Sumter, SC.
47053	GIBSON	TN	27180	Jackson, TN.
47161	STEWART	TN	17300	Clarksville, TN-KY.
48203	HARRISON	TX	30980	Longview, TX.
48431	STERLING	TX	41660	San Angelo, TX.
51097	KING AND QUEEN	VA	40060	Richmond, VA.
51113	MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC.
51620	FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC.
54035	JACKSON	WV	16620	Charleston, WV.
54065	MORGAN	WV	25180	Hagerstown-Martinsburg, MD-WV.
55069	LINCOLN	WI	48140	Wausau-Weston, WI.
72001	ADJUNTAS	PR	38660	Ponce, PR.
72083	LAS MARIAS	PR	32420	Mayagüez, PR.

We proposed that when calculating the area wage index, beginning with CY 2021, the wage data for ESRD facilities located in these counties would be included in their new respective urban CBSAs. We stated in the CY 2021 ESRD PPS proposed rule (85 FR 42157) that typically, ESRD facilities located in an urban area receive a higher wage index value than or equal wage index value to ESRD facilities located in their state's rural area. A discussion of the proposed wage index transition policy is available in section II.B.4.b.(3) of the CY 2021 ESRD PPS proposed rule and section II.B.4.b.(3) of this final rule.

(c) Urban Counties That Would Move to a Different Urban CBSA Under the 2018 OMB Delineations

In the CY 2021 ESRD PPS proposed rule (85 FR 42157 through 42158), we stated that in certain cases, adopting the 2018 OMB delineations would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, we noted that CBSA 19380 (Dayton, OH) would experience both a change to its number and its name, and become CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties would remain the same. We also stated that in other cases, only the name of the CBSA would be modified, and none of the currently assigned counties would be reassigned to a different urban CBSA. In the CY 2021 ESRD PPS proposed rule (85 FR 42158), we listed the CBSAs where there would be a change either in CBSA name or CBSA number, as set forth in Table 3, if we finalized our proposal to adopt the 2018 OMB delineations beginning in CY 2021.

TABLE 3—CY 2021 PROPOSED CHANGE IN CBSA NAME AND/OR NUMBER CROSSWALK

Current CBSA code	Current CBSA title	Proposed CBSA code	Proposed CBSA title
10540	Albany, OR	10540	Albany-Lebanon, OR.
11500	Anniston-Oxford-Jacksonville, AL	11500	Anniston-Oxford, AL.
12060	Atlanta-Sandy Springs-Roswell, GA	12060	Atlanta-Sandy Springs-Alpharetta, GA.
12420	Austin-Round Rock, TX	12420	Austin-Round Rock-Georgetown, TX.
13460	Bend-Redmond, OR	13460	Bend, OR.
13980	Blacksburg-Christiansburg-Radford, VA	13980	Blacksburg-Christiansburg, VA.
14740	Bremerton-Silverdale, WA	14740	Bremerton-Silverdale-Port Orchard, WA.
15380	Buffalo-Cheektowaga-Niagara Falls, NY	15380	Buffalo-Cheektowaga, NY.
19430	Dayton-Kettering, OH	19380	Dayton, OH.
24340	Grand Rapids-Wyoming, MI	24340	Grand Rapids-Kentwood, MI.
24860	Greenville-Anderson-Mauldin, SC	24860	Greenville-Anderson, SC.
25060	Gulfport-Biloxi-Pascagoula, MS	25060	Gulfport-Biloxi, MS.
25540	Hartford-West Hartford-East Hartford, CT	25540	Hartford-East Hartford-Middletown, CT.
25940	Hilton Head Island-Bluffton-Beaufort, SC	25940	Hilton Head Island-Bluffton, SC.

TABLE 3—CY 2021 PROPOSED CHANGE IN CBSA NAME AND/OR NUMBER CROSSWALK—Continued

Current CBSA code	Current CBSA title	Proposed CBSA code	Proposed CBSA title
28700	Kingsport-Bristol-Bristol, TN-VA	28700	Kingsport-Bristol, TN-VA.
31860	Mankato-North Mankato, MN	31860	Mankato, MN.
33340	Milwaukee-Waukesha-West Allis, WI	33340	Milwaukee-Waukesha, WI.
34940	Naples-Immokalee-Marco Island, FL	34940	Naples-Marco Island, FL.
35660	Niles-Benton Harbor, MI	35660	Niles, MI.
36084	Oakland-Hayward-Berkeley, CA	36084	Oakland-Berkeley-Livermore, CA.
36500	Olympia-Tumwater, WA	36500	Olympia-Lacey-Tumwater, WA.
38060	Phoenix-Mesa-Scottsdale, AZ	38060	Phoenix-Mesa-Chandler, AZ.
39150	Prescott Valley-Prescott, AZ	39140	Prescott, AZ.
23224	Frederick-Gaithersburg-Rockville, MD	43524	Silver Spring-Frederick-Rockville, MD.
44420	Staunton-Waynesboro, VA	44420	Staunton, VA.
44700	Stockton-Lodi, CA	44700	Stockton, CA.
45940	Trenton, NJ	45940	Trenton-Princeton, NJ.
46700	Vallejo-Fairfield, CA	46700	Vallejo, CA.
47300	Visalia-Porterville, CA	47300	Visalia, CA.
48140	Wausau, WI	48140	Wausau-Weston, WI.
48424	West Palm Beach-Boca Raton-Delray Beach, FL	48424	West Palm Beach-Boca Raton-Boynton Beach, FL.

In the CY 2021 ESRD PPS proposed rule (85 FR 42159), we explained that ESRD facilities located in an urban area that, due to the 2018 OMB delineations, involves a change only in the CBSA name or number would not experience a consequential change in their wage index value.

However, we also stated that in other cases, if we adopted the 2018 OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. We considered these types of changes, where CBSAs are split into multiple new CBSAs or a CBSA loses one or more counties to another urban CBSAs, to be significant modifications.

In the CY 2021 ESRD PPS proposed rule (85 FR 42160), we listed the urban counties that would move from one urban CBSA to another a newly proposed or modified CBSA, as set forth in Table 4, if we finalized our proposal to adopt the 2018 OMB delineations beginning in CY 2021.

TABLE 4—CY 2021 PROPOSED URBAN TO A DIFFERENT URBAN CBSA CROSSWALK

FIPS county code	County/county equivalent	State	Current CBSA	Current CBSA name	Proposed CBSA code	Proposed CBSA name
17031	COOK	IL	16974	Chicago-Naperville-Arlington Heights, IL.	16984	Chicago-Naperville-Evanston, IL.
17043	DU PAGE	IL	16974	Chicago-Naperville-Arlington Heights, IL.	16984	Chicago-Naperville-Evanston, IL.
17063	GRUNDY	IL	16974	Chicago-Naperville-Arlington Heights, IL.	16984	Chicago-Naperville-Evanston, IL.
17093	KENDALL	IL	16974	Chicago-Naperville-Arlington Heights, IL.	20994	Elgin, IL.
17111	MC HENRY	IL	16974	Chicago-Naperville-Arlington Heights, IL.	16984	Chicago-Naperville-Evanston, IL.
17197	WILL	IL	16974	Chicago-Naperville-Arlington Heights, IL.	16984	Chicago-Naperville-Evanston, IL.
34023	MIDDLESEX	NJ	35614	New York-Jersey City-White Plains, NY-NJ.	35154	New Brunswick-Lakewood, NJ.
34025	MONMOUTH	NJ	35614	New York-Jersey City-White Plains, NY-NJ.	35154	New Brunswick-Lakewood, NJ.
34029	OCEAN	NJ	35614	New York-Jersey City-White Plains, NY-NJ.	35154	New Brunswick-Lakewood, NJ.
34035	SOMERSET	NJ	35084	Newark, NJ-PA	35154	New Brunswick-Lakewood, NJ.
36027	DUTCHESS	NY	20524	Dutchess County-Putnam County, NY.	39100	Poughkeepsie-Newburgh-Middletown, NY.
36071	ORANGE	NY	35614	New York-Jersey City-White Plains, NY-NJ.	39100	Poughkeepsie-Newburgh-Middletown, NY.
36079	PUTNAM	NY	20524	Dutchess County-Putnam County, NY.	35614	New York-Jersey City-White Plains, NY-NJ.
47057	GRAINGER	TN	28940	Knoxville, TN	34100	Morristown, TN.
54043	LINCOLN	WV	26580	Huntington-Ashland, WV-KY-OH.	16620	Charleston, WV.
72055	GUANICA	PR	38660	Ponce, PR	49500	Yauco, PR.
72059	GUAYANILLA	PR	38660	Ponce, PR	49500	Yauco, PR.
72111	PENUELAS	PR	38660	Ponce, PR	49500	Yauco, PR.
72153	YAUCO	PR	38660	Ponce, PR	49500	Yauco, PR.

We stated in the CY 2021 ESRD PPS proposed rule (85 FR 42160), that if ESRD facilities located in these counties move from one CBSA to another under the 2018 OMB delineations, there may be impacts, both negative and positive, to their specific wage index values. A discussion of the proposed wage index transition policy is available in II.B.4.b.(3) of the CY 2021 ESRD PPS proposed rule and section II.B.4.b.(3) of this final rule.

(d) Changes to the Statewide Rural Wage Index

In the CY 2021 ESRD PPS proposed rule (85 FR 42160), we stated that ESRD facilities currently located in a rural area may remain rural under the 2018 OMB delineations but experience a change in their rural wage index value due to the movement of constituent counties. If ESRD facilities located in these counties move from one CBSA to another under the 2018 OMB delineations, there may be impacts, both negative and positive, upon their specific wage index values. A discussion of the proposed wage index transition policy is available in section II.B.4.b.(3) of the CY 2021 ESRD PPS proposed rule and section II.B.4.b.(3) of this final rule.

We explained that we believe these revisions to the CBSA-based labor market area delineations as established in OMB Bulletin 18–04 would ensure that the ESRD PPS area wage level adjustment most appropriately accounts for and reflects the relative wage levels in the geographic area of the ESRD facility. Therefore, we proposed to adopt the 2018 OMB delineations under the ESRD PPS, effective January 1, 2021 and invited public comment on this proposal.

(3) Transition for ESRD Facilities Negatively Impacted

In the CY 2021 ESRD PPS proposed rule (85 FR 42160 through 42161), we stated that in the past we provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts, in order to mitigate the potential impacts of proposed policies on ESRD facilities. For example, we have proposed and finalized budget-neutral transition policies to help mitigate negative impacts on ESRD facilities following the adoption of the OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01 (79 FR 66142). Specifically, as part of the CY 2015 ESRD PPS rulemaking, we implemented a 2-year transition blended wage index for all ESRD facilities. ESRD facilities received 50 percent of their CY 2015 wage index value based on the OMB delineations for CY 2014 and 50 percent of their CY 2015 wage index value based on the newer OMB delineations. This resulted in an average of the two values. Then, in CY 2016, an ESRD facility's wage index value was based 100 percent on the newer OMB delineations.

As we stated in the CY 2021 ESRD PPS proposed rule (85 FR 42161), we considered having no transition period and fully implementing the 2018 OMB delineations beginning in CY 2021, which would mean that all ESRD facilities would have payments based on updated hospital wage data and the 2018 OMB delineations starting on January 1, 2021. However, because the overall amount of ESRD PPS payments would increase slightly due to the 2018 OMB delineations, the wage index budget neutrality factor would be higher. This higher factor would reduce the ESRD PPS per treatment base rate for all ESRD facilities paid under the ESRD PPS, despite the fact that the majority of ESRD facilities would be unaffected by the 2018 OMB delineations. Thus, we explained that we believe it would be appropriate to provide for a transition period to mitigate the resulting short-term instability of a lower ESRD PPS base rate as well as consequential negative impacts to ESRD facilities that experience reduced payments. For example, ESRD facilities currently located in CBSA 35614 (New York-Jersey City-White Plains, NY-NJ) that would be located in new CBSA 35154 (New Brunswick-Lakewood, NJ) under the proposed changes to the OMB delineations would experience a nearly 17 percent decrease in the wage index as a result of the proposed change.

Therefore, under the authority of section 1881(b)(14)(D)(iv)(II) of the Act and consistent with past practice, we proposed a transition policy to help mitigate any significant, negative impacts that ESRD facilities may experience due to our proposal to adopt the 2018 OMB delineations under the ESRD PPS. Specifically, as a transition for CY 2021, we proposed to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior calendar year. This transition would allow the effects of our proposed adoption of the 2018 OMB delineations to be phased in over 2 years, where the estimated reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. We explained that we believe a 5 percent cap on the overall decrease in an ESRD facility's wage index value, regardless of the circumstance causing the decline, would be an appropriate transition for CY 2021 as it would provide predictability in payment levels from CY 2020 to the upcoming CY 2021 and additional transparency because it is administratively simpler than our prior 2-year 50/50 blended wage index approach. We further explained that we believe 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in an ESRD facility's wage index for CY 2021. We solicited comment on the proposal to apply a 5 percent cap on any decrease in an ESRD facility's wage index for CY 2021 from the ESRD facility's wage index from the prior calendar year, CY 2020.

(4) Budget Neutrality Adjustments for Changes to the ESRD PPS Wage Index

In the CY 2021 ESRD PPS proposed rule (85 FR 42161), we stated that consistent with the historical wage index budget-neutrality adjustment policy finalized in the CY 2012 ESRD PPS final rule (76 FR 70241 through 70242) under the authority of section 1881(b)(14)(D)(iv)(II) of the Act, we proposed that the proposed adoption of the 2018 OMB delineations and the proposed transition policy would not result in any change of estimated aggregate ESRD PPS payments by applying a budget neutrality factor to the ESRD PPS base rate. We noted budget neutrality was also applied to the adoption of newer OMB delineations and transition policy in the CY 2015 ESRD PPS final rule (79 FR 66128 through 66129). Our methodology for calculating this budget neutrality factor is discussed in section II.B.4.d.(2) of the CY 2021 ESRD PPS proposed rule and section II.B.4.d.(2) of this final rule.

The comments and our responses to the comments on our proposed adoption of the 2018 OMB delineations are set forth below.

Comment: Several commenters supported the adoption of the 2018 OMB delineations under the ESRD PPS, effective January 1, 2021.

Response: We appreciate the comments supporting the adoption of the 2018 OMB delineations.

Comment: A national non-profit dialysis organization expressed concern that its analysis of the proposal indicates that it will have multiple facilities negatively impacted by the adoption of the 2018 OMB delineations, which is worsened by the current COVID–19 pandemic.

Response: We appreciate the detailed concerns described by the commenter

regarding the impact that the 2018 OMB delineations would have on its specific facilities. While we understand the commenter's concern regarding the potential financial impact, we believe that implementing the 2018 OMB delineations will result in a more accurate representation of labor market areas nationally and in ESRD facility wage index values being more representative of the actual costs of labor in a given area. We believe that the OMB standards for delineating Metropolitan and Micropolitan Statistical Areas are appropriate for determining area wage differences and that the values computed under the revised delineations will result in more appropriate payments to ESRD facilities by more accurately accounting for and reflecting the differences in area wage levels.

We recognize that using the updated OMB delineations will mean there are areas that will experience a decrease in their wage index. As such, it is our longstanding policy to provide a temporary transition to mitigate negative impacts from the adoption of new policies or procedures. In the CY 2021 ESRD PPS proposed rule, we proposed a 2-year transition in order to mitigate the resulting short-term instability and negative impacts on certain ESRD facilities and to provide time for facilities to adjust to their new labor market delineations. We continue to believe that the 1-year 5-percent cap transitional policy provides an adequate safeguard against any significant payment reductions, allows for sufficient time for facilities to make operational changes for future CYs, and provides a reasonable balance between mitigating some short-term instability in ESRD PPS payments and improving the accuracy of the payment adjustment for differences in area wage levels.

We also recognize the impact that the COVID–19 PHE is having on all health care providers, which is why we have issued waivers and flexibilities [19] [20] to ease burden and allow providers to respond effectively during the COVID–19 PHE.

Comment: Several commenters supported the use of a transition policy to mitigate the impact of changes to the wage index values and the proposed transition methodology. Some of these commenters, including MedPAC, suggested alternatives to the methodology. MedPAC suggested that the 5 percent cap limit should apply to both increases and decreases in the wage index so that no ESRD facility would have its wage index value increase or decrease by more than 5 percent for CY 2021.

A patient organization acknowledged the reasoning of CMS proposing a less administratively complex methodology of managing the transition given the relatively small proportion of ESRD facilities that will be affected. The commenter noted that if the total change in payment is 10 percent or less for all facilities, a methodology that caps the decrease in a facility's wage index at 5 percent in the first year makes sense. However, the commenter expressed concern that at least one facility will see a 17 percent decrease in the wage index, which would defer the burden of the transition to the second year. The commenter noted that while providing an extra year for the facility to adjust to the change is helpful, for ESRD facilities that see a drop in wage index payments in the second year and that are located in states without staffing requirements, the negative implications for hiring and retention of staff will be significant. The commenter indicated that it would prefer for CMS to apply the 50/50 blended wage index to manage the transition, but could support the 5 percent cap approach if staff time saved by using a less complex methodology is redirected to addressing higher priority issues, such as securing staff assistance for home dialysis patients or developing a flexible approach to interpretation of the SCI criteria for the TPNIES.

Finally, a national non-profit dialysis organization recommended that CMS provide an extended transition period, beyond the proposed 5 percent limit for 2021, for at least 3 years.

Response: We appreciate the comments supporting the proposed transition methodology. Further, we appreciate MedPAC's suggestion that the 5 percent cap should also be applied to increases in the wage index. However, as we discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42161), the purpose of the proposed transition policy, as well as those we have implemented in the past, is to help mitigate the significant negative impacts of certain wage index changes, not to curtail the positive impacts of such changes, and thus we do not believe it would be appropriate to apply the 5 percent cap on wage index increases as well. To the extent that an ESRD facility's wage index would increase under the 2018 OMB delineations, this means that the ESRD facility is currently being paid less than their reported wage data suggests is appropriate. We believe the transition policy, as proposed, would help ensure these ESRD facilities do not receive a wage index adjustment that is lower than appropriate and that payments are as accurate as possible.

With regard to recommendation that we apply the 50/50 blended wage index to manage the transition since some facilities will see a wage index decrease greater than 10 percent, we believe that this approach would not be appropriate for the proportion of ESRD facilities that will be impacted. The use of a 50/50 blended wage index transition would affect all ESRD facilities. We believe it would be more appropriate to allow ESRD facilities that would experience an increase in their wage index value to receive the full benefit of their increased wage index value, which is intended to reflect accurately the higher labor costs in that area. The utilization of a cap on negative impacts restricts the transition to only those with negative impacts and allows ESRD facilities who would experience positive impacts to receive the full amount of their wage index increase. As such, we believe a 5 percent cap on the overall decrease in an ESRD facility's wage index value is an appropriate transition as it would effectively mitigate any significant decreases in an ESRD facility's wage index for CY 2021. With regard to the comment suggesting staff time be used to address higher priority issues, we believe that the comment was referring to CMS staff. We appreciate the commenter's recommendation for polices that impact home dialysis and innovation.

With regard to the suggestion that we extend the transition period, beyond the proposed 5 percent limit for CY 2021, for at least 3 years, we believe this would undermine the goal of the wage index policy, which is to improve the accuracy of payments under the ESRD PPS. Extending the transition period and applying a cap would serve to further delay improving the accuracy of the ESRD PPS by continuing to pay certain ESRD facilities more than their wage data suggest is appropriate. Therefore, while we believe that a transition policy is necessary to help mitigate some initial significant negative impacts from the revised OMB delineations, we also believe this mitigation must be balanced against the importance of ensuring accurate payments.

The general comments received on the CY 2021 ESRD PPS wage index and our responses to the comments are set forth below.

Comment: Two health insurance organizations in Puerto Rico commented on the wage index for Puerto Rico. One health insurance organization in Puerto

[19] *https://www.cms.gov/files/document/qso-20-19-esrd-revised.pdf.*

[20] *https://www.cms.gov/files/document/covid-19-esrd-facilities.pdf.*

Rico expressed appreciation for the wage index floor of 0.5000 and explained that it represents an important acknowledgment of the many complexities associated with providing dialysis in Puerto Rico. The commenter noted that in the post-hurricane environment particularly, infrastructure challenges lead to high costs of dialysis care. The commenter strongly encouraged CMS to continue to look closely at the wage index as it relates to Puerto Rico.

One of the health insurance organizations asserted that a wage index floor of 0.70 would result in rates that more accurately reflect actual cost per treatment based on costs after multiple natural disasters and the disruptions in 2020 due to COVID–19. The commenter expressed concern that the financial viability of dialysis providers in Puerto Rico is under stress and that it is in the interest of beneficiaries, the Medicare program, and the fragile healthcare infrastructure in Puerto Rico to have available multiple competing dialysis services providers. The commenter stated that the average in-center HD costs for independent facilities in Puerto Rico is $232.25 per treatment using CMS data from 2017. The commenter asserted that this number is significantly higher than the average FFS payment rate for Puerto Rico and significantly lower than the rates contracted by Medicare Advantage companies for the same service. The commenter noted that in-center HD represents the majority of the treatments for Puerto Rico ESRD patients. The commenter suggested that CMS consider basing the ESRD wage index on a new survey of ESRD outpatient facility wage costs as a means for wage index reform.

Both health insurance organizations referred to the wage index policy changes included in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42332). Specifically, the commenters urged that the FFS ESRD PPS wage index system for Puerto Rico should use the recently adjusted inpatient facility (Part A) wage index values to reverse the wage index ''downward spiral'' consistently across all Medicare payment systems. Finally, they recommended that CMS assure that the corresponding adjustment in Medicare Advantage benchmarks for ESRD is made to reflect any adjustments in ESRD PPS payments.

Response: We did not propose specific policies relating to the wage index floor. We thank the commenters for sharing their concerns regarding Puerto Rico's wage index and their suggestions for wage index reform, along with the recommendation of a wage index for Puerto Rico of 0.70 and their concern regarding the Medicare Advantage benchmarks for ESRD. We will take these thoughtful suggestions into consideration when considering future rulemaking.

Final Rule Action: After considering the comments received, for the reasons set forth in this final rule and in the CY 2021 ESRD PPS proposed rule, we are finalizing our proposal to adopt the newer OMB delineations contained in OMB Bulletin 18–04 as proposed. We are also finalizing our proposal to apply a 5 percent cap on any decrease in an ESRD facility's wage index for CY 2021 from the ESRD facility's wage index from the prior calendar year (CY 2020) as proposed. We did not receive comments on our proposal regarding wage index budget neutrality, therefore we are finalizing the application of a budget neutrality factor to the ESRD PPS base rate to ensure that the adoption of the 2018 OMB delineations and the transition policy will not result in any change of estimated aggregate ESRD PPS payments.

We are finalizing the CY 2021 ESRD PPS wage indices based on the latest hospital wage data as proposed. For CY 2021, the labor-related share to which a facility's wage index is applied is 52.3 percent.

The final CY 2021 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.* Addendum A provides a crosswalk between the CY 2020 wage index for an ESRD facility using the current OMB delineations in effect in CY 2020, the CY 2021 wage index using the current OMB delineations in effect in CY 2020, and the CY 2021 wage index using the final 2018 OMB delineations. Addendum B provides an ESRD facility-level impact analysis. Addendum B includes the final transition wage index values that will be in effect in CY 2021. Addendum B is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.*

c. CY 2021 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of ESAs necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities, such as secondary hyperparathyroidism. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237. The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundle: (1) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (4) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (5) Renal dialysis equipment and supplies that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs that were or would have been covered under Medicare Part D for

outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed Medicare allowable payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted and described in the following paragraphs) plus the fixed-dollar loss (FDL) amount. In accordance with § 413.237(c), facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and at § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments.

In the CY 2020 ESRD PPS final rule (84 FR 60705), we stated that based on the CY 2018 claims data, outlier payments represented approximately 0.5 percent of total payments. We also noted that, beginning in CY 2020, the total expenditure amount includes add-on payment adjustments made for calcimimetics under the TDAPA policy. We projected that for each dialysis treatment furnished, the average amount attributed to the TDAPA would be $21.03 (84 FR 60704).

For CY 2021, we proposed that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2019. As we stated in the CY 2021 ESRD PPS proposed rule (85 FR 42162), because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we proposed that the outlier thresholds for CY 2021 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2019. We noted that, for CY 2020, the total expenditure amount includes add-on payment adjustments made for calcimimetics under the TDAPA policy (calculated to be $14.87 per treatment). However, as discussed in section II.B.1 of this final rule, for CY 2021 we modified the ESRD PPS base rate by adding $9.93 to account for calcimimetics in the ESRD PPS bundled payment and will no longer pay for these drugs using the TDAPA. In addition, we are finalizing that beginning January 1, 2021, calcimimetics will be eligible outlier services.

As discussed in section II.B.4.c.(2) of this final rule, CY 2019 claims data show outlier payments represented approximately 0.5 percent of total payments. As we stated in the CY 2021 ESRD PPS proposed rule, we recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS. We stated that, for CY 2021, the adult predicted outlier services MAP amounts and FDL amounts have increased as a result of our incorporation of oral and injectable calcimimetics into the outlier policy.

(1) CY 2021 Update to the Outlier Services MAP Amounts and FDL Amounts

For this final rule, the outlier services MAP amounts and FDL amounts were updated using 2019 claims data. The impact of this update is shown in Table 5, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2020 with the updated estimates for this final rule. The estimates for the CY 2021 outlier policy, which are included in Column II of Table 5, were inflation adjusted to reflect projected 2021 prices for outlier services.

TABLE 5—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I final outlier policy for CY 2020 (based on 2018 data, price inflated to 2020) *		Column II final outlier policy for CY 2021 (based on 2019 data, price inflated to 2021)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$30.95	$37.33	$30.33	$53.08
Adjustments				
Standardization for outlier services	1.0655	0.9781	1.0390	0.9789
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$32.32	$35.78	$30.88	$50.92
FDL amount that is added to the predicted MAP to determine the outlier threshold	$41.04	$48.33	$44.78	$122.49
Patient-months qualifying for outlier payment	11.35%	10.38%	8.80%	5.15%

Note: Column I was obtained from Column II of Table 2 from the CY 2020 ESRD PPS final rule (84 FR 60705).

As demonstrated in Table 5, the estimated FDL amount per treatment that determines the CY 2021 outlier threshold amount for adults (Column II; $122.49) is higher than that used for the CY 2020 outlier policy (Column I; $48.33). The higher threshold is accompanied by an increase in the adjusted average MAP for outlier services from $35.78 to $50.92. For pediatric patients, there is an increase in the FDL amount from $41.04 to $44.78 and a decrease in the adjusted average MAP for outlier services, from $32.32 to $30.88.

As we stated previously, the predicted outlier services MAP amounts and FDL amounts have increased as a result of the incorporation of oral and injectable calcimimetics into the outlier policy. Approximately 30 percent of ESRD beneficiaries receive calcimimetics and a subset of these beneficiaries tend to have the highest ESRD PPS expenditures, which trigger outlier payments under the ESRD PPS. Since the highest per-beneficiary ESRD PPS expenditures will increase due to calcimimetics being eligible ESRD outlier services, the outlier FDL will increase to ensure that total outlier payments project to 1 percent of total Medicare ESRD PPS expenditures.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2021 will be 5.15percent for adult patients and 8.80 percent for pediatric patients, based on the 2019 claims data. The outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of calcimimetics, ESAs and other injectable drugs).

(2) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. Based on the 2019 claims, outlier payments represented approximately 0.5 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. Recalibration of the thresholds using 2019 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2021.

We believe the update to the outlier MAP and FDL amounts for CY 2021 will increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy because we are using more current data for computing the MAP and FDL, which is more in line with current outlier services utilization rates. The inclusion of calcimimetics as ESRD outlier services in CY 2021 will fundamentally change the per-treatment distribution of outlier services relative to previous CYs. In 2019 claims, roughly 33 percent of ESRD beneficiaries and 28 percent of dialysis treatments are associated with calcimimetics and those that often have significantly higher utilization of ESRD outlier services relative to beneficiaries who do not receive calcimimetics. The MAP and FDL increases account for this change. We note that recalibration of the FDL amounts in this final rule will result in no change in payments to ESRD facilities for beneficiaries with renal dialysis services that are not eligible for outlier payments.

The comments and our responses to the comments on our proposed updates to the outlier policy are set forth below.

Comment: Although we did not propose changes to the outlier target percentage or methodology for computing the MAP or FDL amounts, we received many comments from MedPAC, national dialysis associations, large dialysis organizations, non-profit dialysis associations, a patient advocacy organization, and an academy of nutrition and dietetics expressing concern that the outlier policy has not been effective. Most of the commenters opposed the proposed changes to the MAP and FDL along with suggestions that ranged in complexity for the policy's reform, which are described in detail below. We also received data from the commenters' analysis that studied the impact of outlier payments once calcimimetics become ESRD outlier services.

All commenters noted that since the beginning of the ESRD PPS, the outlier pool has not paid out the full amount withheld each year. MedPAC noted that every year the outlier threshold has been reduced and yet still turns out to have been set too high. MedPAC stated that this phenomenon suggests a declining trend in the use of outlier-eligible services (that is, drugs and laboratory services that were separately billable under the prior payment system) for ESRD beneficiaries with very high estimated spending on those services. MedPAC asserted that CMS' strategy of updating the base year of data used to calculate the outlier threshold to bring the outlier payments closer to the targeted 1 percent, has not been effective.

Many commenters recommended that CMS adjust the outlier percentage to more accurately represent the percentage of total payments that have been historically paid under the outlier policy. For example, commenters suggested that CMS reduce the outlier pool withheld to less than 1 percent, indicating that they believe this approach to be consistent with the intent of Congress since a minimum percentage was not set in the legislation. One non-profit dialysis organization recommended removing the outlier provision from the bundled payment system but recognized that the provision is required by statute and suggested that the percentage be decreased from 1 percent to 0.5 percent. A few other commenters agreed with reducing the percentage to 0.5 and recommended that CMS finalize this change for CY 2021.

An LDO recommended that CMS establish a mechanism to return unpaid amounts withheld from ESRD facilities as part of the target percentage when it does not achieve the 1 percent outlier policy in a given year. An academy of nutrition and dietetics made a similar comment and stated when these dollars are paid back to ESRD facilities they would be invested in patient care.

A national dialysis association stated that CMS is correctly adding resources to the ESRD PPS bundled payment to help continued patient access to calcimimetics after the end of the TDAPA period, but this correct policy decision creates adverse, unintended consequences for the outlier pool that must be mitigated in the final rule.

Several commenters opposed the proposal to increase the adult FDL and MAP outlier amounts accounting for the calcimimetics. Some commenters, including MedPAC, stated that this action could further exacerbate the longstanding issue of the outlier pool being underpaid. MedPAC identified two problems that are additive; meaning the outlier payments may be too low because (1) the outlier threshold calculation does not account for the trend of decreasing spending for services previously eligible for an outlier payment; and (2) in making calcimimetics eligible for outlier payments in CY 2021, the outlier threshold calculation does not account for the likelihood that calcimimetic use will be lower after payment for calcimimetics is added to the ESRD PPS bundled payment. MedPAC indicated that the fact that CMS is proposing to increase the outlier threshold by 126 percent in 2021, rather than decrease the threshold as the agency has done in every other year, corroborates the reliance on high calcimimetic use for receiving an outlier payment in 2021. MedPAC further stated that, if calcimimetic use decreases between

2019 (when the products were paid using the TDAPA) and 2021 (when the products will be paid as part of the ESRD PPS base rate), the outlier threshold will be set too high and outlier payments will be lower than the 1 percent of total 2021 payments.

Several commenters urged CMS to lower the thresholds proposed for 2021. The commenters expressed concern that increases to the outlier threshold would cause a shift in the cases qualifying for an outlier payment. They stated that the increases to the thresholds would limit most outlier payments to those patients who use IV calcimimetics, largely excluding outlier payments for the care of patients using other relatively high-cost items and services that otherwise would be eligible for outliers absent adoption of the proposed substantial increases to the outlier thresholds. Many commenters referred to a study performed by the Moran Company which was submitted in a comment letter from a national dialysis organization. The study demonstrated that as a result of the proposed policy changes to increase the outlier thresholds, 76.3 percent of the outlier pool will be dedicated solely to patients that utilize calcimimetics, leaving few resources for other high-cost patients.

Several commenters expressed concern that the dynamic shift of the allocation of outlier payments seen in the Moran Company's analyses for calcimimetics would continue to happen in the future when new therapies become ESRD outlier services. One commenter explained that any new product that qualifies for the outlier policy and has a significant cost associated with it will lead to higher threshold amounts. Several commenters referred to MedPAC's public comment for the CY 2020 ESRD PPS rulemaking, in which MedPAC recommended that CMS exclude payments during a TDAPA—or TPNIES—period from outlier pool calculations given that CMS policy makes a drug or equipment or supply ineligible for outlier payments during the add-on period. The commenters described this as a policy misalignment that causes outlier payments to be less than the outlier target percentage.

Two commenters suggested comprehensive refinement of the outlier policy methodology. MedPAC recommended that CMS consider an approach that reflects the trend in separately billable spending over time. MedPAC noted that other CMS payment systems use trend information when establishing similar payment policies. For example, in establishing county benchmark rates, MedPAC stated that the Medicare Advantage program uses a prediction method that accounts for utilization trends for specific services combined with the most recent available prices. MedPAC asserted that such an approach could produce a more reliable outlier threshold estimate and may result in the outlier payment amounts that, on average, are closer to the target.

Several commenters recommended that CMS explore reserving a portion of the outlier pool to be in proportion to the share of new ESRD outlier services, in this case calcimimetics, compared to the current spending on all other ESRD outlier services in the ESRD PPS. Under this type of policy, CMS could establish a MAP and fixed-loss amount for each sub-pool. The total value of the outlier pool could remain at 1 percent (or less as noted above) of the ESRD PPS. CMS could recalculate the size of the sub-pool based on the most recently available claims data. Over time, CMS could evaluate whether additional functional categories (in addition to bone and mineral metabolism) would merit the creation of additional sub-pools. One national kidney dialysis organization explained that in addition to allowing the outlier pool to address higher-costs patients outside of the calcimimetic costs, the distributed nature of the sub-pools would decrease the risk of dollars being removed from the payment system unintentionally.

A national dialysis association provided a simulation of the calculation of outlier payments performed by the Moran Company testing two sub-pools of the outlier withhold: One for patients using calcimimetics and another for other, high cost patients who do not use calcimimetics. The Moran Company found that use of sub-pools would improve the distribution of outlier payments for all high cost patients, but indicated that it is not likely to eliminate all leakage from the ESRD PPS due to the outlier pool. The commenter stated that this finding underscores the need to reduce the withhold amount to 0.5 percent and correct the misalignment between CMS's policies that withhold dollars during an add-on payment period when the treatment is not eligible for outlier payments. The commenter urged CMS to include its recommended approach to bifurcate the outlier policy in the CY 2021 ESRD PPS final rule. The commenter suggested that CMS could publish an interim final rule with comment period, if needed, to ensure that the public can comment on these proposals prior to implementation. However, the commenter emphasized that these policies should take effect for CY 2021 to ensure that the outlier pool continues to support high cost patients under the ESRD PPS.

Many commenters expressed interest in working with CMS to refine the outlier policy methodology to make sure that it addresses the needs of all types of high costs patients. The commenters suggested that a larger discussion of a solution to the outlier pool being dominated by a single product is warranted, perhaps through a TEP or in another forum.

Response: We appreciate all of the thoughtful suggestions provided by commenters. We acknowledge that, even with annually adjusting the MAP and FDL to reflect the most recent utilization and costs of ESRD PPS eligible outlier services, total outlier payments have not yet reached the 1 percent target. However, it is also true that use of eligible ESRD outlier services declined each year. That is, ESRD facilities incurred lower costs than anticipated, and those savings accrued to facilities more than offsetting the extent to which the consequent outlier payments fell short of the 1.0 percent target.

We appreciate the comments suggesting solutions for refining the outlier policy methodology, for example, reducing the outlier percentage pool withhold to less than 1 percent or establishing a mechanism that pays back ESRD facilities those allocated outlier amounts that did not pay out in the year projected. We also appreciate the comments suggesting more complex solutions, such as the approach provided by MedPAC, that uses trend information for establishing thresholds or the approach from other commenters that bifurcates the outlier pool into sub-pools. We did not propose any changes to the outlier policy methodology in the CY 2021 ESRD PPS proposed rule. Our proposal was limited to updating the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2019 claims. Therefore, we are not finalizing these significant methodological changes the commenters suggested.

However, we recognize that the incorporation of calcimimetics into the ESRD PPS bundled payment system, and of which effective January 1, 2021 are ESRD PPS eligible outlier services, brings with them a unique dynamic. As the commenters have indicated, these products are expensive and these high costs have been loaded into the projections for the outlier payments. We also agree with the commenters that as new therapies become eligible ESRD outlier services, they too will bring significant costs that could further

complicate the allocation of outlier payments to beneficiaries that may not be using the particular new therapy. As we noted in the previous paragraph, we do not believe it is appropriate to finalize significant methodological changes, such as bifurcating the outlier pool into sub-pools, without performing detailed analyses to inform us on the implications of the changes. Similarly, we do not agree with the suggestion that CMS publish an interim final rule with comment period to finalize complex changes to the outlier policy methodology so that they can take effect in CY 2021; doing so would be premature since we would not have carefully studied and considered the potential consequences.

We appreciate the commenters' expressed interest in working with CMS to refine the outlier policy methodology to make sure that it addresses the needs of all types of high costs patients. While commenters suggested a TEP or another forum to develop a solution to the outlier pool being dominated by a single product, we had already indicated in the CY 2020 ESRD PPS final rule (84 FR 60607) that a TEP would address the outlier policy as part of the efforts to refine the ESRD PPS. Following publication of the CY 2020 ESRD PPS final rule, a TEP was held in December 2019. The outlier policy was on the agenda and our data contractor discussed: The current approach to outlier payments, stakeholder concerns regarding the current outlier payment, an alternative methodology to achieve the 1 percent outlier target, and feedback on the proposed approach.

Under the alternative approach discussed at the TEP, the underlying basis of the alternative methodology is to relax the assumption of constant utilization of eligible outlier services over time, which allows for the modeling of the MAP amounts as they change over time. It also allows for the use of data from a greater number of years to inform trends. Details regarding the session dedicated to the outlier policy are available on the CMS website: *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-december.pdf.*

We believe that the information gathered at the TEP and the thoughtful suggestions provided in the public comments submitted in response to the CY 2021 ESRD PPS proposed rule can be taken into consideration in the future as we explore ways to refine the outlier policy methodology.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2021 displayed in Column II of Table 5 of this final rule and based on CY 2019 data.

d. Final Impacts to the CY 2021 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we established the methodology for calculating the ESRD PPS per-treatment base rate, that is, ESRD PPS base rate, and the determination of the per-treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, any applicable outlier payment and training adjustment add-on, the TDAPA, and the TPNIES.

(2) Annual Payment Rate Update for CY 2021

We are finalizing an ESRD PPS base rate for CY 2021 of $253.13. This update reflects several factors, described in more detail as follows:

- *Wage Index Budget-Neutrality Adjustment Factor:* We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2021, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2021 wage index budget-neutrality adjustment factor using treatment counts from the 2019 claims and facility-specific CY 2020 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2020. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2021. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD PPS wage index for CY 2021. As discussed in section II.B.4.b of this final rule, the final ESRD PPS wage index for CY 2021 includes an update to the most recent hospital wage data, the adoption of the 2018 OMB delineations, and a 5 percent cap on wage index decreases applied for CY 2021. The total of these payments becomes the new CY 2021 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2021 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2021 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The final CY 2021 wage index budget-neutrality adjustment factor is .999485. This application would yield a CY 2021 ESRD PPS base rate of $239.21, ($239.33 × .999485 = $239.21), prior to the addition to the ESRD PPS base rate to include calcimimetics and the application of the final market basket increase.
- *Addition to the ESRD PPS Base Rate to Include Calcimimetics:* As discussed in section II.B.1 of this final rule, for CY 2021 we are modifying the ESRD PPS base rate by adding $9.93 to account for calcimimetics in the ESRD PPS bundled payment. This application would yield a CY 2021 ESRD PPS base rate of $249.14 ($239.21 + $9.93 = $249.14), prior to the application of the final market basket increase.
- *Market Basket Increase:* Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest projection of the ESRDB market basket percentage increase factor for CY 2021 is 1.9 percent. In CY 2021, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously, the final MFP adjustment for CY 2021 is 0.3 percentage point, thus yielding an update to the base rate of 1.6 percent for CY 2021. Therefore, the final CY 2021

ESRD PPS base rate is $253.13 ($249.14 × 1.016 = $253.13).

In summary, we are finalizing a CY 2021 ESRD PPS base rate of $253.13. This amount reflects a CY 2021 wage index budget-neutrality adjustment factor of .999485, an addition of $9.93 to the ESRD PPS base rate to include calcimimetics, and the CY 2021 ESRD PPS payment update of 1.6 percent.

The comments and our responses to the comments on our updates to the CY 2021 ESRD PPS base rate are set forth below.

Comment: Commenters were supportive of the updates to the ESRD PPS base rate for CY 2021.

Response: We appreciate the comments in support of the updates.

Comment: An academy of nutrition and dietetics urged CMS to consider access to care in rural areas when setting the rates under the ESRD PPS. The commenter referred to MedPAC's March 2020 Report to Congress,[21] and noted MedPAC's concern about the gap in the Medicare margin between rural and urban facilities. The commenter believes that the proposal to cap any decrease in an ESRD facility's wage index is one way to address these access to care concerns, including access to registered dietitian nutritionists (RDNs). The commenter explained that RDNs perform many roles in ESRD facilities aimed at improving outcomes and promoting therapy adherence, including dialysis treatments, dietary recommendations, and medication regimes. The commenter expressed concern that there are significant challenges to the hiring and retention of RDNs in rural area ESRD facilities, therefore rates for the rural facilities require an adequate margin to support recruitment and retention of qualified RDNs to address the needs of this nutritionally high-risk population.

Response: We appreciate the commenter's recommendation for CMS to consider access to care in rural areas when setting the rates under the ESRD PPS, specifically with regard to hiring and retaining specialized staff that provide quality care to ESRD beneficiaries. As we stated in the CY 2020 ESRD PPS final rule (84 FR 60701), the annual update factor is intended to account for the overall increase in cost of care at the national level. The patient case-mix payment adjustments and the facility level adjustments, such as the rural adjustment and low-volume payment adjustment account for differences in both patient and facility characteristics. These payment adjustments are provided to address the variation of costs of a particular facility relative to the national standard. The CY 2016 ESRD PPS final rule discusses the methodology for calculating the patient and facility-level adjustments (80 FR 68972 through 69004). In addition, the ESRD PPS base rate is adjusted for any applicable outlier payment, training add-on payment, the TDAPA, and the TPNIES to arrive at the per treatment payment amount.

For these reasons, we believe that the CY 2021 ESRD PPS base rate is appropriate despite the challenges some ESRD facilities experience. We also continue to believe that the payment adjustments, such as the rural adjustment and the low volume payment adjustment help mitigate the challenges faced by those facilities that are eligible for the adjustments.

Final Rule Action: We are finalizing a CY 2021 ESRD PPS base rate of $253.13.

5. Changes to the Low-Volume Payment Adjustment

a. Background

As required by section 1881(b)(14)(D)(iii) of the Act, the ESRD PPS includes a payment adjustment that reflects the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. We have established a LVPA factor of 23.9 percent for ESRD facilities that meet the definition of a low-volume facility. Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation—(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and (2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year. Under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question.

For purposes of determining eligibility for the LVPA, ''treatments'' mean total HD-equivalent treatments (Medicare and non-Medicare as well as ESRD and non-ESRD). For PD patients, 1 week of PD is considered equivalent to 3 HD treatments. As noted previously, we base eligibility on the 3 years preceding the payment year and those years are based on cost reporting periods. Specifically, under § 413.232(g), the ESRD facility's cost reports for the periods ending in the 3 years preceding the payment year must report costs for 12-consecutive months (76 FR 70237).

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its MAC confirming that it meets all of the requirements specified in § 413.232 and qualifies as a low-volume ESRD facility. The attestation is required because: (1) ESRD facility's cost reporting periods vary and may not be based on the calendar year; and (2) the cost reports are due 5 months after the close of the cost reporting period (that is, there is a lag in the cost reporting submission). Thus, the MACs may not have the cost report for the third year to determine eligibility and would need to rely on the attestation for that year until the cost report is available. Section 413.232(e) imposes a yearly November 1 deadline for attestation submissions, with a few exceptions where the deadline is December 31. The November 1 timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236).

As stated in the Medicare Benefit Policy Manual, (Pub. L. 100–02), (chapter 11, section 60.B.1),[22] once the attested ESRD facility's cost report is submitted to the MAC, the MAC verifies the as-filed cost report for the third eligibility year and finds that the ESRD facility met the eligibility criteria, the ESRD facility would then receive the LVPA payment for all the Medicare-eligible treatments in the payment year. However, if the attested ESRD facility's cost report for the third eligibility year exceeds the total dialysis treatment threshold, then the MAC recoups by reprocessing claims paid during the payment year in which the ESRD facility incorrectly received the LVPA. Recoupment also occurs if any cost reports used for eligibility are subsequently found to have not met the low-volume criteria, for example, reopening or appeals.

Further information regarding the administration of the LVPA is provided

[21] *http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch6_sec.pdf?sfvrsn=0.*

[22] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

in the Medicare Benefit Policy Manual, chapter 11, section 60.B.1.[23]

b. Revisions to the LVPA Requirements and Regulations

As we discussed in the CY 2019 ESRD PPS final rule (83 FR 56949) and the CY 2021 ESRD PPS proposed rule (85 FR 42165), we have heard from stakeholders that low-volume facilities rely on the LVPA and loss of the adjustment could result in beneficiary access issues. Specifically, stakeholders expressed concern that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility in certain circumstances.

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42165), according to the Centers for Disease Control and Prevention (CDC), the risk factors for COVID–19 include older adults and people of any age who have serious underlying medical conditions, such as diabetes and chronic kidney disease undergoing dialysis. Medicare's ESRD population aligns with the profile of patients who are more susceptible to COVID–19. As a result, ESRD facilities are working together to keep the risk of spreading COVID–19 down as much as possible by shifting patients among the ESRD facilities in the same area. In some cases, this shifting of patients has caused some low-volume ESRD facilities to temporarily dialyze patients that they otherwise would not have dialyzed if there had not been a PHE. In addition, since cases of acute kidney injury (AKI) have increased in certain areas of the country due to COVID–19, there is also an increase in the number of patients discharged that need outpatient dialysis for some period of time while their kidneys regain normal function. We expressed concern that these increases in dialysis treatments due to the COVID–19 PHE in CY 2020 may put certain low-volume facilities over the LVPA's treatment threshold causing the loss of, or the inability to qualify for, the 23.9 percent per treatment payment adjustment for payment years 2021, 2022, and 2023. We noted that in CY 2020, 338 ESRD facilities receive the LVPA. We also noted that in a typical year, we estimate that between 50–60 facilities lose their LVPA status. That is, there are between 50–60 ESRD facilities that typically lose their LVPA status because their patient population grew for reasons other than the COVID–19 PHE.

In light of the unique circumstance due to the COVID–19 PHE, we proposed to hold ESRD facilities harmless if an increase in their treatment counts in 2020 is COVID–19-related such that the increase would prevent them from qualifying for the LVPA. We proposed that the ESRD facility would attest that the increase in treatments, meaning total HD-equivalent treatments (for ESRD and AKI), was temporary and related to the redistribution of patients in response to the COVID–19 PHE. When this occurs, instead of using total dialysis treatments furnished in cost reporting periods ending in 2020, CMS would rely on the facility's attestation that the increase in total dialysis treatments was due to the PHE for the COVID–19 pandemic. We proposed that for purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, we would only consider total dialysis treatments furnished for 6 months of a facility's cost-reporting period ending in 2020, and that an ESRD facility would decide which 6 months to use (consecutive or non-consecutive) for purposes of reporting total treatments. That is, ESRD facilities would attest that, while it furnished 4,000 or more treatments in its cost-reporting period ending in 2020, the number of treatments exceeding the allowed threshold to otherwise qualify for the LVPA was due to temporary patient shifting as a result of the COVID–19 PHE, and that their total dialysis treatments for any 6 months of that period is less than 2,000. MACs would annualize the total dialysis treatments for those 6 months by multiplying by 2. ESRD facilities would be expected to provide supporting documentation to the MACs upon request.

We proposed to revise § 413.232(g) by adding paragraph (g)(4) to reflect that, for purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, an ESRD facility's attestation must indicate that the ESRD facility meets all the LVPA criteria except that, for a facility that does not otherwise meet the number-of-treatments criterion (that is, less than 4,000 in a year) because of the COVID–19 PHE, the facility furnished less than 2,000 treatments in any 6 months during its cost-reporting period ending in 2020 due to temporary patient shifting as a result of the COVID–19 PHE. We also proposed that the MAC would rely on the facility's attestation and would annualize the total dialysis treatments for the 6 months by multiplying those collective 6 month treatments by 2.

In addition, since CMS changed cost reporting deadlines due to the COVID–19 PHE, we believe the extraordinary circumstances of the COVID–19 pandemic justify an exception to the November 1, 2020 attestation deadline. Therefore, for payment year 2021, we proposed to allow more time for ESRD facilities to submit attestations by extending the deadline to December 31, 2020. We would reflect this change in § 413.232(e) by reformatting the section to reflect already established exceptions to the November 1 attestation deadline in paragraphs (e)(1) through (3), and to include in new paragraph (e)(4) that, for payment year 2021, the attestation must be provided by December 31, 2020.

We proposed a technical change at § 413.232(b) to remove the heading ''Definition of low-volume facility'' to be consistent with the current CFR requirements.[24]

We also proposed a technical change at § 413.232(e) and (g). We proposed to add ''MAC'' in § 413.232(e) to establish the acronym for Medicare Administrative Contractor. We proposed to replace ''Medicare Administrative Contractor (MAC)'' with ''MAC'' in § 413.232(g) since the acronym would now be established in § 413.232(e).

c. Clarification for MAC LVPA Determinations

As we discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42166), in order to receive the LVPA, an ESRD facility must meet the requirements of § 413.232, including submitting attestations to the MACs indicating its eligibility for the adjustment. In its attestation for the third eligibility year, which is the cost-reporting year immediately preceding the payment year, a facility attests that it will be eligible for the adjustment; this attestation typically occurs prior to the MAC having the facility's cost report for the third eligibility year, in which case the MAC relies on the facility's attestation to determine if the facility qualifies for the LVPA. When an ESRD facility qualifies for the adjustment, the LVPA would be applied to all the Medicare-eligible treatments for the entire payment year. If the MAC subsequently determines, however, that the ESRD facility failed to qualify for the LVPA, and the facility had already begun to receive the adjustment to which the MAC has determined it is not entitled, the MAC would reprocess the claims to remove and recoup the low-volume payments.

We understand that in some instances, MACs may be discontinuing LVPA payments to a facility in the payment year for which the facility is eligible for the adjustment. However,

[23] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

[24] Document Drafting Handbook, chapter 2, section 2.10, page 2–18: *https://www.archives.gov/files/federal-register/write/handbook/ddh.pdf.*

the established policy is such that, if an ESRD facility meets the LVPA eligibility criteria in § 413.232, it is entitled to the payment adjustment for the entire payment year. Because there may be some inconsistent application of this policy, we are taking this opportunity to make this aspect of the LVPA policy clear in the regulation text.

We proposed to revise § 413.232 by adding paragraph (h) to specify that, if an ESRD facility provides an attestation in accordance with § 413.232(e) for the third eligibility year, the MAC verifies the as-filed cost report. If the MAC determines an ESRD facility meets the definition of a low-volume facility, CMS adjusts the low-volume facility's base rate for the entire payment year. However, if the MAC determines an ESRD facility does not meet the definition of a low-volume facility, the MAC reprocesses claims and recoups low volume adjustments paid during the payment year.

The comments and our responses to the comments on our LVPA proposals are set forth below.

Comment: Several commenters expressed support for the proposal to hold harmless ESRD facilities that would otherwise qualify for the LVPA but for a temporary increase in dialysis treatments due to the PHE for the COVID–19 pandemic. Two of the commenters indicated that holding these ESRD facilities harmless will better ensure ESRD patients' access to life-sustaining dialysis.

Response: We appreciate the support of the commenters as we strive to ensure access to care during this unprecedented time.

Comment: One commenter expressed concern that the intent of the proposal would not be met as the length of the PHE for COVID–19 remains uncertain.

Response: We thank the commenter for its support for the proposed LVPA modifications while appreciating this concern. While the end of the PHE for COVID–19 remains uncertain, we believe that the modification adequately address the current and foreseen impact of COVID–19 on low volume ESRD facilities. We will consider the COVID–19 PHE during rulemaking in the future, if warranted.

Comment: One commenter expressed confusion over the proposed methodology, indicating that LVPA attestation data can be pulled from any six-month period in the preceding three years. The commenter expressed concern that facilities who would have exceeded the threshold, even in the absence of COVID–19, can 'mask' their disqualification.

Response: We acknowledge the commenter's confusion over the proposal. For purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023, the facility would attest that its total dialysis treatments for those 6 months of their cost-reporting period ending in 2020 are less than 2,000 and that, although the total number of treatments furnished throughout the entire year otherwise exceeded the LVPA threshold of 4,000, the excess treatments are a direct result of patient shifting from the COVID–19 PHE. ESRD facilities would select 6 months (consecutive or non-consecutive) of total dialysis treatments furnished for purposes of the LVPA determination and, if eligible, will receive the benefit for the entire payment year. If the ESRD facility would have not qualified for the LVPA in the absence of COVID–19, the facility cannot attest that the COVID–19 PHE caused its excess treatments. The policy is intended to directly address the burden placed on ESRD facilities in 2020 due to the COVID–19 PHE. Future rulemaking will address the PHE's impact on the LVPA, if the impact continues into following years.

Comment: We received comments that suggested we adopt a methodology including a combination of the rural and LVPA adjusters to create a tiered LVPA, targeting facilities providing less than 4,000 treatments per year, and expanding the adjuster to include a second tier that includes facilities providing less than 6,000 treatments per year.

Response: We appreciate commenters' suggestions for an alternative methodology and will take their suggestions into consideration for future rulemaking.

Final Rule Action: After consideration of public comments, for CY 2021, we are finalizing the revisions to the LVPA, as proposed. We are finalizing the revision to § 413.232(g) by adding paragraph (g)(4) to codify the process. We are also finalizing the proposal to reformat § 413.232(e) to reflect already established exceptions to the November 1 attestation deadline in paragraphs (e)(1) through (3), and to include in new paragraph (e)(4) that, for payment year 2021, the attestation must be provided by December 31, 2020. We are finalizing a technical change at § 413.232(b) to remove the heading ''Definition of low-volume facility.'' We are also finalizing technical changes at § 413.232(e) and (g), whereby ''MAC'' would be added in § 413.232(e) to establish the acronym for Medicare Administrative Contractor and ''MAC'' would replace ''Medicare Administrative Contractor (MAC)'' in § 413.232(g). Lastly, we are finalizing the revision of § 413.232 by adding paragraph (h) to specify that, if an ESRD facility provides an attestation in accordance with § 413.232(e) for the third eligibility year, the MAC verifies the as-filed cost report.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies for CY 2021 Payment

1. Background

In the CY 2020 ESRD PPS final rule, we finalized the establishment of a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) to support ESRD facilities in the uptake of certain new and innovative renal dialysis equipment and supplies under the ESRD PPS. Under our current regulation at § 413.236(b), we will provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) Has been designated by CMS as a renal dialysis service under § 413.171, (2) is new, meaning it is granted marketing authorization by FDA on or after January 1, 2020, (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter and related guidance; and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired). Specifically, the equipment or supply must represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Under the first criterion, as reflected in the CY 2020 ESRD PPS final rule, renal dialysis equipment and supplies will be considered ''new'' if FDA grants them marketing authorization on or after January 1, 2020. By including FDA marketing authorizations on or after January 1, 2020, we intended to support ESRD facility use and beneficiary access to the latest technological improvements to renal dialysis equipment and supplies. We note that in section II.B.2.b of this final rule, we are refining the newness criterion (year in which the product was granted FDA marketing

authorization) and establish that an equipment or supply is considered ''new'' within 3 years beginning on the date of FDA marketing authorization for that equipment or supply. For capital-related assets that are dialysis machines when used in the home setting for a single patient, the 3 years would begin from the date of FDA marketing authorization for home use. We note that the changes to the newness criteria and the other changes discussed in section II.B.2.b are effective beginning January 1, 2021, that is, applicable for the TPNIES applications received in 2021.

As we stated in the CY 2021 ESRD PPS proposed rule (85 FR 42166), we believed the IPPS SCI criteria and the process used to evaluate SCI under the IPPS could be used for identifying new and innovative equipment and supplies worthy of additional payment under the ESRD PPS. We noted that under the IPPS, CMS has been assessing new technologies for many years to assure that the additional new technology add-on payments to hospitals are made only for truly innovative and transformative products, and we stated that CMS is proposing to adopt the IPPS SCI criteria under the ESRD PPS for the same reason. We explained that we wanted to ensure that the add-on payment adjustments made under the ESRD PPS are limited to new equipment and supplies that are truly innovative. In addition, since renal dialysis services are routinely furnished to hospital inpatients and outpatients, we stated that we believed the same SCI criteria should be used to assess whether a new renal dialysis equipment or supply warrants additional payment under Medicare.

We finalized the adoption of IPPS's SCI criteria specified in § 412.87(b)(1), including modifications finalized in future IPPS final rules, to determine when a new and innovative renal dialysis equipment or supply is eligible for the TPNIES under the ESRD PPS. That is, we would adopt IPPS's SCI criteria in § 412.87(b)(1) and any supporting policy around these criteria as discussed in IPPS preamble language. We stated that we believed that by incorporating the IPPS SCI criteria for new and innovative renal dialysis equipment under the ESRD PPS, we would be consistent with IPPS and innovators would have standard criteria to meet for both settings. We also proposed to establish a process modeled after IPPS's process of determining if a new medical service or technology meets the SCI criteria specified in § 412.87. That is, we proposed that CMS would use a similar process to determine whether the renal dialysis equipment or supply meets the eligibility criteria proposed in newly added § 413.236(b). Similar to how we evaluate whether a new renal dialysis drug or biological product is eligible for the TDAPA, as discussed in the CY 2016 ESRD PPS final rule (80 FR 69019), we would need to determine whether the renal dialysis equipment and supply meets our eligibility criteria for the TPNIES.

Specifically, under § 413.236(b)(5) we evaluate SCI for purposes of the TPNIES under the ESRD PPS based on the IPPS SCI criteria (see § 412.87(b)(1)). We note that in the CY 2021 ESRD PPS proposed rule as well as section II.B.2.a of this final rule, we provide a detailed discussion of the SCI criteria. In addition, in section II.B.2.b of this final rule we are revising § 413.236(b)(5) to remove ''and related guidance'' to reflect that all related SCI guidance has now been incorporated into § 412.87(b)(1).

As we discussed in the CY 2021 ESRD PPS proposed rule and in section II.B.2.a of this final rule, we established in § 413.236(c) a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b). Then, after consideration of public comments we will announce the results in the **Federal Register** as part of our annual ESRD PPS final rule. We noted we would only consider a complete application received by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. We note in section II.B.2.b of this final rule, we are revising § 413.236(c) to replace ''September 1'' with ''the HCPCS Level II code application deadline for Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website'' to reflect that FDA marketing authorization for the new and innovative equipment or supply must accompany the HCPCS application prior to the particular calendar year in order for the item to qualify for the TPNIES in the next calendar year.

2. Applications for TPNIES Payment for CY 2021

We received two applications for the TPNIES for CY 2021. A discussion of these applications is presented below.

a. Theranova 400 Dialyzer and Theranova 500 Dialyzer

(1) Baxter Healthcare Corporation (Baxter) Application

Baxter submitted an application for the Theranova 400 Dialyzer/Theranova 500 Dialyzer. The 400 and 500 denote differences in surface area. The applicant stated that Theranova represents an SCI over currently available HD therapies for the treatment of renal failure. The applicant stated that Theranova is a new class of hollow-fiber, single-use dialyzer intended to treat renal failure by HD. The applicant stated that it features an innovative 3-layer membrane structure that offers a higher permeability than high-flux dialyzers, with improved removal of large proteins up to 45 kilodaltons (kDa) while selectively maintaining essential proteins such as albumin.[25] [26] [27] The applicant stated that Theranova has the potential to transform in-center HD by allowing Medicare beneficiaries with renal failure to benefit from expanded hemodialysis (HDx). HDx is defined as a process of blood purification that includes the clearance of small uremic toxins through large middle molecule (LMM) (categorized as uremic solute whose molecular size is 25 kDa up to 60 kDa) toxins without the need for an external infusion of replacement fluid. For purposes of the application, HDx is collectively referred to in the application as ''Theranova''. The applicant asserted that the Theranova dialyzer integrates with existing HD machines that an ESRD facility already owns and that the Theranova dialyzer replaces other dialyzers.

The applicant described the Theranova membrane as unique and stated it allows for the removal of an expanded range of solutes, creating a filtration profile closer to a natural kidney. The applicant described the membrane structure as being divided into three distinct layers: A fingerlike porous outer layer, a sponge-like intermediate layer, and a very thin inner layer (skin). By reducing the inner diameter of the membrane, internal filtration is increased, allowing for enhanced clearance of LMMs through

[25] Boschetti-de-Fierro, A., et al., ''MCO Membranes: Enhanced Selectivity in High-Flux Cases,'' *www.nature.com/Scientific Reports,* [5:18448] DOI: 10.1038/srep18448.

[26] Krause, B., et al., ''Highly selective membranes for Blood purification,'' Gambro Dialysatoren GmbH, Hechingen/Germany, Presentation abstract March 26, 2015.

[27] Zweigart, C., et al., ''Medium cut-off membranes—closer to the natural kidney removal function,'' *Int. J Artif Organs,* 2017, 40(7), pp. 328–334. DOI: 10.5301/uijao.5000603.

additional convective transport.[28] The Theranova dialyzer enables the efficient removal of uremic toxins (up to 45 kDa).[29] [30] The applicant included an adapted figure from a book titled, ''Modelling and Control of Dialysis Systems [31] to compare removal of toxins by Theranova to the kidney and to other dialysis therapies, such as low flux dialyzers (LF), high flux dialyzers (HFD) and hemodiafiltration (HDF). The applicant's adapted figure showed the following: LF, HFD, HDF and HDx remove urea (60 Daltons (Da)), phosphate (96 Da), Parathyroid hormone (9,500 Da); HFD, HDF and HDx remove Beta 2 microglobulin (12 kDa), cystatin C (13 kDa), Myoglobulin (17 kDa), and, kappa free-light-chains (23 kDa); HDF and HDx remove complement factor D (24 kDa), Interleukin (IL)–6 (25 kDa), alpha 1 microglobulin (33 kDa); and, HDx removes Chitinase-3-like protein 1 (40 kDa), lambda free-light-chains (45 kDa) and albumin (67 kDa).

The applicant stated that compared with low-flux HD, high-flux HD, and HDF, the Theranova dialyzer filtration profile is more similar to that of a natural kidney, as shown *in vitro* [32] [33] giving it expanded clearance of uremic toxins.

The applicant asserted that the design of the Theranova dialyzer allows for use on any HD machine, made by any manufacturer, by merely changing the dialyzer. The applicant stated that the membrane is compatible with standard fluid quality and does not require any additional fluid quality control measure.

Theranova received approval for Investigational Device Exemption (IDE) protocol from the FDA, on August 31, 2017, and then received approval for coverage on September 13, 2017. The Class II investigational device exemption received the code G170157.[34] The FDA requested a 6-month clinical study to validate efficacy of large toxin removal and safety. According to the applicant, safety is defined in part by albumin loss. The applicant stated that it is seeking marketing authorization through the FDA's De Novo pathway and marketing authorization this year for the May 2020 cycle. The applicant stated that it plans to submit a HCPCS application to CMS in June 2020.

The applicant noted that it has not submitted an application for pass-through payments under the Medicare Outpatient Prospective Payment System (OPPS) or the NTAP program under the Medicare IPPS for the Theranova 400 Dialyzer/Theranova 500 Dialyzer.

The applicant stated that it expects Theranova to be commercially available immediately after receiving marketing authorization and will provide proof of commercial availability.

With regard to demonstrating the requirements for SCI, the applicant asserted that Theranova represents an SCI in outcomes for Medicare beneficiaries over currently available HD therapies treating renal failure. The applicant noted that ESRD patients on current HD therapies suffer unsatisfactorily high mortality and morbidity from cardiovascular disease and infections.[35]

In addition, the applicant stated that the HDx enabled by Theranova effectively targets the removal of LMM uremic toxins (25 kDa to 60 kDa), which are linked to the development of inflammation, cardiovascular disease, and other comorbidities in dialysis patients. The applicant stated that this results in improved clinical outcomes, relative to current dialyzers in four clinical categories. First, a decreased rate of subsequent therapeutic interventions, including fewer infections, reduced hospitalization duration, and reduced medication usage. Specifically, the applicant stated that patients treated with HDx therapy have decreased infections. A prospective cross-over study found an average of seven episodes of infection for patients treated with HDx versus 18 for high flux HD (p = 0.003).[36] The applicant also stated that patients receiving HDx therapy with Theranova had hospital stays averaging 4.4 days versus 5.9 days for patients receiving traditional HD (p = 0.0001) along with lower hospitalization rates (71 percent versus 77 percent (p = 0.69)).[37] The U.S. IDE Randomized Controlled Trial (NCT032574 l 0) of 172 patients, although not powered for all-cause hospitalization events, showed a 49 percent decreased number of hospitalization events in the Theranova arm (18 events) as compared to the control arm (37 events).[38] With regard to improved medication usage, the applicant stated that patients receiving HDx therapy had reduced medication usage. The applicant cited three studies that showed a significant decrease in erythropoietin stimulating agents (ESA) usage.[39] [40] [41] One study also found a substantial reduction in the need for iron usage.[42] [43] Two studies saw an improvement in EPO resistance index (ERI) and one study showed a statistically significant decrease in phosphate binder (calcium carbonate) usage.[44] [45]

The second clinical improvement category listed by the applicant is a more rapid beneficial resolution of the disease process treatment. The applicant cited a 2019 publication which noted that the average recovery time after dialysis is reduced with HDx therapy, with the median self-reported recovery time at 120 minutes, 60 min., 60 min., and 105 min. at 3, 6, 9, and 12 months compared to a baseline 240 min. ($p < 0.01$ for 6, 9, and 12-month ratings; N = 110).[46]

The third category of improved clinical outcomes listed by the applicant

[28] Lorenzin, A., et al., ''Quantification of Internal Filtration in Hollow Fiber Hemodialyzers with Medium Cut-Off Membrane,'' *Blood Purif,* 2018, 46, pp. 196–204.

[29] Boschetti-de-Fierro, A., et al., ''MCO Membranes: Enhanced Selectivity in High-Flux Cases,'' *www.nature.com/Scientific Reports,* [5:18448] DOI: 10.1038/srep18448.

[30] Boschetti-de-Fierro, A., et al., ''MCO Dialyzers: Enhanced Selectivity High-Flux,'' Gambro Dialysatoren GmbH, Research and Development, Hechingen, Germany, Poster No. SAT–481 (Baxter).

[31] Azar, A.T. and Canaud, B., ''Chapter 8: Hemodialysis System,'' *Modeling and Control of Dialysis Systems,* 2013, pp. 99–106, SCI 404 Berlin, Springer-Verlag, Berlin, Heidelberg. ISBN: 978–3642274572.

[32] Krause, B., et al., ''Highly selective membranes for Blood purification,'' Gambro Dialysatoren GmbH, Hechingen/Germany, Presentation abstract March 26, 2015.

[33] Boschetti-de-Fierro, A., et al., ''MCO Membranes: Enhanced Selectivity in High-Flux Cases,'' *www.nature.com/Scientific Reports,* [5:18448] DOI: 10.1038/srep18448.

[34] Available on p. 49828 at: *https://www.federalregister.gov/documents/2017/10/27/2017-23447/medicare-and-medicaid-programs-quarterly-listing-of-program-issuances-july-through-september-2017.*

[35] United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

[36] Cozzolino, C., et al., ''Effects of a medium cut-off (Theranova) dialyzer on haemodialaysis patients: A prospective, cross-over study,'' *Clinical Kidney Journal,* 2019, pp. 1–8. Doi 10.1093/ckj/sfz 155.

[37] Sanabria, R.M., et al. ''Expanded Hemodialysis and its effects on hospitalizations and medication usage,'' Submitted for publication.

[38] Weiner, D.E., et al. 2019, ''Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Control Trial,'' Abstract at ASN meeting, FR–PO 488.

[39] Gallo, M., ''The Real-Life Study on Expanded Hemodialysis (HDx): 9 Months Experience of a Single Hemodialysis Unit,'' *Nephrology Dialysis Transplantation,* 34, Issue Supplement_1, June 2019, gfz106.FP539, *https://doi.org/10.1093/ndt/gfz106.FP539.*

[40] Sanabria, R.M., et al., Ibid.

[41] Lim, J–H., et al., ''Novel Medium Cut-Off Dialyzer Improves Erythropoietin Stimulating Agent Resistance in Maintenance Hemodialysis Patients: A Randomized Controlled Trial,'' Manuscript submitted for publication.

[42] Sanabria, R.M., et al., Ibid.

[43] Lim, J–H., et al., Ibid.

[44] Sanabria, R.M., et al., Ibid.

[45] Lim, J–H., et al. Ibid.

[46] Bolton, S., et al., ''Dialysis symptom burden and recovery time in expanded hemodialysis,'' Manuscript submitted.

is reduced inflammation in patients receiving HDx Therapy with Theranova. The applicant referenced a 2018 review article, which notes that chronic inflammation in ESRD patients is associated with the build-up of known uremic toxins spanning the molecular size spectrum from 12 kDa to 45 kDa such as beta-2-microglobulin, soluble tumor necrosis factor (TNF), Receptor 2, IL–1, Prolactin, IL–18, IL–6, Hyaluronic Acid, TNF–a, Soluble TNF Receptor 1, Pentraxin–3, and Advanced Glycation End-Products. The same article notes the following: (1) LMM (25 kDa to 60 kDa) have been associated with inflammation, cardiovascular events and other dialysis-related comorbidities; (2) current dialytic therapies, though efficient in removing small solutes, have limited capability in removing LMM; (3) current dialyzer design, limited by membrane permeability, does not provide long-lasting, effective reduction of the full spectrum of small molecular uremic toxins (<500 Da), conventional middle molecular uremic toxins (500 Da to <25 kDa) and large middle molecular uremic toxins (25 kDa to 60 kDa), even when their usage is enhanced with convective transport; and (4) a broad spectrum of uremic toxins are not effectively treated by conventional HD nor HDF which is not readily utilized in the U.S.[47] The applicant asserted that for the first time, HDx enabled by Theranova results in the superior removal of the aggregate of small, conventional middle and large middle molecular uremic toxins.[48] The applicant asserted that Theranova, in effectively targeting the spectrum of uremic toxins, that this spectrum encompasses the totality of these inflammation-modulating molecules.

The applicant also asserted that when analyzing the full set of studies utilizing Theranova dialyzers, the collective evidence shows consistent improvement in these inflammatory marker levels. Of 14 measurements of inflammation across four studies,[49 50 51 52] 71 percent (10 of 14) showed statistically significant improvement in the inflammatory marker. For the remaining 29 percent of the measured inflammatory markers, all showed improvement in the inflammatory profile but were not statistically significant. In most of the situations where statistically significant results were not achieved, the applicant asserted, the studies were underpowered to demonstrate statistically significant change of the particular marker.

The applicant stated that studies have demonstrated stable albumin levels,[53 54] and a reduction of endothelial dysfunction and Albumin and C–Reactive Protein (CRP) levels.[55 56 57] In addition, the applicant specifically described a single cohort study (N = 41) showing a significant decrease in serum levels for urea, β2m, kappa and lambda free light chain at 3 months. At 3 and 6 months, there was a substantial decrease in serum CRP levels. Also, blood assay demonstrated a decline in the production of IL–6.[58] In a 40-participant cross-over prospective study, HDx with Theranova versus high flux HD demonstrated both a higher reduction ratio and a decrease in serum levels for lambda free light chains.[59 60 61]

The applicant also noted that, in addition to IL–6, a well-recognized biological marker of inflammation, there is also a broader spectrum of uremic toxins associated with inflammation. The applicant listed references for elevated levels of IL–6 leading to the following: Hepcidin production with decreased iron availability;[62] increased endothelial damage;[63 64] increased CRP and decreased albumin production.[65] The applicant attested that with the use of Theranova, patients present clinically with the opposite of each of the above listed concerns, suggesting that chronic inflammation mediated by IL–6 is reduced by treatment with Theranova. However, the applicant submitted a reference that concluded that when compared to HD using high flux membrane, HD using a medium cut-off (MCO) membrane may not be inferior in albumin loss.[66]

An additional prospective cross-over study (N=20) showed reduced levels of IL–6 (6.4561.57 pg/m vs. 9.4862.15 pg/ml) in patients treated with HDx.[67] The applicant included findings from their U.S. IDE Study in the TPNIES application. Although the IL–6 level was not a primary endpoint of the US IDE Study (NCT03257410), nor was the study sufficiently powered to statistically prove a change in IL–6 level, the analysis of the US IDE Study (NCT032574 l 0), comparing Theranova to HD with Elisio 17H, indicates a trend for difference in the pre- to post-dialysis change in plasma IL–6 level, favoring Theranova (p=0.07 and p=0.08 at 4 weeks and 24 weeks, respectively). The pre-dialysis level of IL–6 shows a

[47] Wolley, M., et al., ''Exploring the Clinical Relevance of Providing Increased Removal of Large Middle Molecules,'' *Cli, J Am Soc Nephrol,* 2018, 13, pp. 805–813.

[48] Kirsch AH, Lyko R, Nilsson LG., et al. Performance of hemodialysis with novel medium cut-off dialyzers. Nephrol Dial Transplant 2017; 32: 165–172.

[49] Belmouaz, M., et al., ''Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High Flux Dialyzers: A Randomized Clinical Trial,'' *Nephrol Dial Transplant,* 2020, 35, pp. 328–335.

[50] Kharbanda, K., et al., ''A Randomised Study Investigating the Effect of Medium Cut-Off Haemodialysis on Markers of Vascular Health Compared with On-Line Haemodiafiltration (MoDal Study)''. Poster presented at the American Society of Nephrology, 2019.

[51] Cozzolino, M., ''Effects of Mediun Cut-Off (Theranova) Dialyzer on Hemodialysis Patients: A Prospective Cross-Over Study [Abstract].'' J Am Soc Nephrol, 29. 2018, pp. 616–617.

[52] Cantaluppi, V., et al., ''Removal of Large Middle Molecules on Expanded Hemodialysis (HDx): A Multicentric Observantional Study of 6 Months Follow-Up,'' *J Am Soc Nephrol,* 29, 2018, Poster TH–PO 357.

[53] Krishnasamy, R., et al., ''Trial evaluating mid cut-off value membrane clearance of albumin and light chains in hemodialysis patients (REMOVAL–HD): A safety and efficacy study,'' 2018, ASN 2018 Kidney Week Abstract TH–P0353.

[54] Bunch, A., et al., ''Long-Term Effects of Expanded Hemodialysis (HDx) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis Patients,'' 2018, ASN 2018 Kidney Week Abstract FR–P0766.

[55] Kharbanda, K., et al. 2019, Ibid.

[56] Cantaluppi, V., et al., Ibid.

[57] Cantaluppi, V., et al., ''Removal of Large-Middle Molecules, Inhibition of Neutrophil Activation and Modulation of Inflammation-Related Endothelial Dysfunction During Expanded Hemodialysis (HDx),'' June 2019, Nephrol Dial Transplantation, 34, Issue Supplement_1. gfz096.FO048, *https://doi.org/10.1093/ndt/gfz096.FO048.*

[58] Cantaluppi, V., et al., Ibid.

[59] Belmouaz, M., et al., ''Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High Flux Dialyzers: A Randomized Clinical Trial,'' J Am Soc Nephrol, 2018, 29, Poster TH–PO348.

[60] Belmouaz M, et al., ''Comparison of hemodialysis with medium cut-off dialyzer and on-line hemodiafiltration on the removal of small and middle-sized molecules,'' Clin Nephrol. Jan 2018, 89 (2018)(1):50–56.

[61] Belmouaz, M., et al., ''Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High-Flux Dialyzers: A Randomized Clinical Trial,'' Nephrol Dial Transplant, 2020, 35, pp. 328–335.

[62] Caramelo, C., et al., ''Anemia: Pathophysiology, pathogenesis, treatment, incognitate,'' Rev Esp Cardiol., 2007, 60, pp. 848–60.

[63] Kharbanda, K., et al., ''A randomized study investigating the effect of medium cut off haemodialysis on markers of vascular health compared with on-line hemodiafiltration (MoDal Study),'' *2019,* Presented at the Scientific Congress American Society of Nephrology, 2019.

[64] Cozzolino, C., et al., ''Effects of a medium cut-off (Theranova) dialyzer on haemodialaysis patients: A prospective, cross-over study,'' *Clinical Kidney Journal,* 2019, pp. 1–8. Doi 10.1093/ckj/sfz 155.

[65] Gillerot, G., et al. ''Genetic and Clinical Factors Influence the Baseline Permeability of the Peritoneal Membrane,'' *Kidney Int.* 2005, 67, pp. 2477–2487.

[66] Jung, J.H., et al., ''A 6-Month Study on the Efficacy of Hemodialysis Therapy Using Dialyzers with Mediun Cut-Off Membranes in Asian Patients with End-Stage Renal Disease,'' *Nephrol Dial Transplant,* June 2019. 84, Issue Supplement, gfz103.SP487, *https://doi.org/10.1093/ndt/gfz103.SP487.*

[67] Cozzolino, C., et al., 2019, Ibid.

positive trend for Theranova (p=0.2).[68] The applicant stated that the accumulation of IL–6 and lambda free light chains may contribute to the chronic inflammation state of ESRD patients, increasing the risk of chronic vascular disease and bacterial infections, respectively. The applicant noted that the company is exploring options to assess the impact of the reduction of these solutes via HDx in ongoing studies.

Finally, the last category of improved clinical outcomes listed by the applicant is enhanced quality of life across many different measures, including, but not limited to, decreased recovery time, decreased restless leg syndrome, and reduced pruritus. The applicant stated that there was decreased symptom burden, citing a study of patients who switched to HD_x with Theranova in a multicenter 6-month observational study (N=992), who had statistically significant improvements in measures of symptoms of kidney disease, effects of kidney disease, and the burden of kidney disease.[69] The applicant also stated that there was improved reported mental health component and statistically significant reduced Restless Leg Syndrome diagnosis.[70 71 72 73] Regarding improved physical functioning and decreased pruritus, the applicant submitted an article reporting the results of a randomized control trial (N=50), where Theranova resulted in improved results for physical functioning and physical role, and the mean scores of mean pruritus distribution and frequency of scratching during sleep were significantly lower with Theranova.[74] In another study (single cohort, N=14), Theranova was associated with statistically significant improvement in the physical and mental component quality of life measures.[75] The applicant also submitted a case report of a HD patient with pruritus who responded to the initiation of HD_x using a MCO dialysis membrane.[76]

(2) CMS Analysis

(a) Summary of Submitted Evidence of the Theranova Dialyzer by CMS

CMS evaluated the claims and assertions made by Baxter with regard to the articles submitted by them for the Theranova Dialyzer.

Patients with ESRD requiring dialysis are at high risk of mortality due to the presence of uremic toxins.[77] However, identifying the putative uremic toxin (or toxins) has proven challenging; the European Uremic Toxin Work Group previously identified at least 90 compounds that are retained in patients undergoing dialysis.[78] Current HD technology relies on diffusion of toxins across a semi-permeable membrane to allow for the removal of small-sized (<500 Da) water-soluble molecules. While HD is generally able to remove water-soluble small toxins (<500 Da), HD has limited ability to clear protein bound solutes, those that are sequestered, or LMM solutes (>500 Da).[79 80 81] The accumulation of uremic toxins with higher molecular weight is associated with immunodeficiency, inflammation, protein-wasting, and cardiovascular complications. For instance, solutes such as Beta-2 microglobulin (11.8 kDa)[82 83] are associated with increased mortality.[84] Protein-bound solutes such as indoxyl sulfate and p-cresol sulfate also appear to be poorly dialyzable and are associated with the uremic syndrome and cardiovascular disease.[85]

While dialysis can eliminate the immediate risk of death from uremia, it does not replace functioning kidneys. Patients receiving adequate dialysis do not completely recover from the uremic syndrome, indicating that other uremic toxins may not fully be cleared.[86 87] Compared to the general population, patients with ESRD who receive dialysis are at an increased risk of death, commonly suffer from uremic symptoms such as itching, restless legs, and malnutrition, and are at increased infection risk. Conventional dialysis is effective in removing small molecules, but is less effective in removing larger molecules, sequestered molecules, and protein-bound toxins. Accumulation of middle molecule and protein-bound toxins may contribute to adverse outcomes among patients receiving dialysis[88] and may explain why even a small amount of ''residual'' kidney function is strongly associated with increased survival[89 90] and higher quality of life.[91 92]

[68] Weiner, D.E., et al., 2019 ''Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Control Trial,'' Abstract at ASN meeting, FR–P.O. 488.

[69] Alarcon, J.C., et al., ''Real World Evidence on the Impact of Expanded Hemodialysis (HD_x) Therapy on Patient Reported Outcomes (PROs): COREXH Registry,'' Manuscript submitted for Publication.

[70] Alarcon, J.C., Manuscript submitted for publication, Ibid.

[71] Gernone, G., et al., ''Mid-term Evaluation of the New Medium Cut-Off Filter (Theranova) on Removal Efficiency and Quality of Life,'' *Nephrology Dialysis Transplantation,* 2018, ERA EDTA Scientific Congress Abstract, SP 489, doi.10.1093/ndt/gfy104.

[72] Florens, N and Juillard, L., ''Expanded haemodialysis: News from the field,'' *Nephrol Dial Transplant,* 2018, 33, pp. iii48–iii52.

[73] Bunch, A., et al. ''Long-Term Effects of Expanded Hemodialysis (HD_x) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis Patients'' ASN 2018 Kidney Week Abstract FR–P0766.

[74] Lim, J–H., et al. ''Novel medium cut off dialyzer improves erythropoietin stimulating agent resistance in maintenance hemodialysis: A randomized controlled trial,'' Submitted for publication.

[75] Gernone, G., et al., ''Mid-term Evaluation of the New Medium Cut-Off Filter (Theranova) on Removal Efficiency and Quality of Life,'' *Nephrology Dialysis Transplantation,* 2018, ERA EDTA Scientific Congress Abstract, SP 489, doi.10.1093/ndt/gfy104.

[76] Penny, J., et al. ''Pruritus: ls there a salty truth?'' Submitted for publication.

[77] Boschetti-de-Fierro, A., et al., ''MCO Membranes: Enhanced Selectivity in High-Flux Cases,'' *www.nature.com/Scientific Reports,* [5:18448] DOI: 10.1038/srep18448.

[78] Vanholder R, et al., European Uremic Toxin Work Group (EUTox). Review on uremic toxins: Classification, concentration, and interindividual variability. *Kidney Int,* 2003 May; 63 (5):1934–43.

[79] Macías N., et al., ''Middle molecule elimination in expanded haemodialysis: only convective transport'' *Clin Kidney J.,* Dec. 2018, 15;12 (3), pp. 447–455.

[80] García-Prieto, A., et al., ''Evaluation of the efficacy of a medium cut-off dialyser and comparison with other high-flux dialysers in conventional haemodialysis and online haemodiafiltration.'' *Clin Kidney J.,* Oct. 2018, 11(5):742–746.

[81] Dobre, M., et al., ''Searching for Uremic Toxins'' *Clinical Journal of American Society of Nephrology.* February 2013, 8 (2) 322–327.

[82] Belmouaz, M., et al. ''Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High-Flux Dialyzers: A Randomized Clinical Trial,'' *J Am Soc Nephrol,* 29, 2018, Poster TH–PO348.

[83] Belmouaz, M., et al., ''Comparison of hemodialysis with medium cut-off dialyzer and on-line hemodiafiltration on the removal of small and middle-sized molecules,''*Clin Nephrol.* Jan 2018, 89 (2018)(1):50–56.

[84] Cordeiro, I., et al.'' High-Flux versus High-Retention-Onset Membranes: In vivo Small and Middle Molecules Kinetics in Convective Dialysis Modalities,'' *Blood Purification,* Jul 2019, 30:1–8.

[85] Vanholder, R., et al., ''Protein-bound uremic solutes: The forgotten toxin,'' *Kidney International.* Feb 2001, 59 (78), S266–S270.

[86] Tanaka H, Sirich TL, Plummer NS, Weaver DS, Meyer TW. An Enlarged Profile of Uremic Solutes. PLoS One. 2015; 10(8): e0135657.

[87] Sirich, T.L, et al., ''The Frequent Hemodialysis Network Trial Group. Limited reduction in uremic solute concentrations with increased dialysis frequency and time in the Frequent Hemodialysis Network Daily Trial.Kidney Int, May 2017, 91 (5): 1186–1192.doi:10,1016/j.kint.2016.11.002.Epub 2017 Jan 12.

[88] Clark, W.R., et al. ''Uremic Toxins and their Relation to Dialysis Efficacy.'' *Blood Purif.,* 2019,48(4), pp.299–314. Epub 2019 Sep 27.

[89] Obi, Y., et al., ''Residual Kidney Function Decline and Mortality in Incident Hemodialysis Patients,'' *J Am Soc Nephrol.,* Dec. 2016, 27(12), pp. 3758–3768. Epub 2016 May 11.

[90] Wang, A.Y. and Lai, K.N. ''The importance of residual renal function in dialysis patients.'' *Kidney Int.,* May, 2006, 69(10), pp. 1726–32.

[91] Dobre, M., et al., ''Searching for Uremic Toxins'' *Clinical Journal of American Society of Nephrology.* February 2013, 8 (2) 322–327.

[92] Bargman, J.M., et al., ''CANUSA Peritoneal Dialysis Study Group. Relative contribution of residual renal function and peritoneal clearance to adequacy of dialysis: A reanalysis of the CANUSA

Continued

Innovations in dialysis care include the development of technologies that might remove potential toxins resistant to clearance using current devices. One technology called HDF removes larger molecules by combining convection with diffusion. Convection relies on pressure gradients across the dialyzer membrane, leading to more effective removal of middle to large molecules from the blood. Substantial fluid losses with convection, must be replaced via infusion of typically ultrapure water and dialysis fluids.[93] This newer technology was later supplemented by online HDF, which enables dialysis providers with ultrapure water systems to generate replacement fluid solution. Although HDF has been associated with improvements to survival in retrospective, observational studies,[94] randomized controlled trials have been less consistent.[95 96 97 98] Online HDF has become more widely used in Europe, but it not commonly used in the U.S. due to costs associated with the need for ultrapure water.[99]

Newer dialysis membranes aimed at improved middle molecule clearance are an active area of research.[100] High flux membranes with larger pore sizes can remove larger molecules, including inflammatory cytokines and immunoglobulin light chains but at the cost of albumin loss.[101] This is significant because low albumin levels are associated with higher mortality rates in patients with ESRD.[102]

In addition to potential risks associated with efforts to remove larger molecules during dialysis (such as the loss of albumin and immunoglobulins), benefits of improved middle molecule clearance have not been demonstrated in large, randomized-controlled trials. In 2002, a large multicenter randomized controlled trial (HEMO) compared patients receiving maintenance dialysis via high-flux versus low-flux dialyzer membranes. There was no difference in the primary endpoint (death from all causes) or in secondary endpoints (hospitalizations for cardiac cause or death, and hospitalizations for infection or death) between the two groups. In rhabdomyolysis, myoglobin clearance has been demonstrated with large pore dialyzers and HDF, but clinical benefit remains largely unproven.[103] Similarly, HDF has historically garnered much attention in sepsis due to its ability to efficiently clear inflammatory cytokines like IL–6, but numerous studies have shown no mortality benefit in sepsis with possible downsides in the form of shortened filter life.[104] No trials have examined the potential benefit of removing larger quantities of middle molecules than is typically achieved from high-flux membranes.

The clearance of protein-bound and sequestered molecules remains a technical challenge and may explain why HDF and other technologies aimed at improved middle-molecule clearance have not significantly changed clinical outcomes.[105] Theoretically, intensive, long-duration dialysis should improve the clearance of these difficult to remove substances.[106] In practice, large, randomized trials have not shown any difference in the level of substances like indoxyl sulfate and p-cresol sulfate.[107 108] Improving clearance of these molecules could improve clinical outcomes in patients without residual renal function and would be a boon to the dismal outcomes faced by patients undergoing dialysis.

(b) Assessment of Substantial Similarity to Currently Available Equipment or Supplies

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42171), with regard to the criterion as to whether Theranova uses the same or a similar mechanism of action to achieve a therapeutic outcome, CMS believes that this product slightly modifies existing HD technology. A MCO membrane was designed for use in HD (but not HFD or HDF) modes. These modifications include the removal of larger molecules and increased convection compared to existing HD. As to whether the new use of the technology involves treatment of the same or similar type of disease and the same or similar patient population, CMS noted that Theranova treats similar patients, specifically, patients with ESRD.

(c) Preliminary Assessment of SCI (see §§ 413.236(b)(5) and 412.87(b)(1)) by CMS

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42171), with regard to the SCI criteria, we noted that Theranova is a treatment modality and does not offer the ability to diagnose a medical condition as discussed in § 412.87(b)(1)(ii)(B). We noted that Theranova does not offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The patients who are eligible for this treatment would also be eligible for HD, HDF, or online HDF. CMS carefully analyzed the evidence submitted as to whether Theranova significantly improves the treatment and clinical outcomes of Medicare beneficiaries relative to renal dialysis services previously available as demonstrated by the totality of the circumstances. Below, we have summarized the clinical evidence for claims of SCI, along with the additional references submitted by

Study,'' *J Am Soc Nephrol.,* Oct. 2001, 12(10), pp. 2158–62.

[93] Zweigart, C., et al., ''Medium cut-off membranes—closer to the natural kidney removal function,'' *Int. J Artif Organs,* 2017, 40(7), pp. 328–334. DOI: 10.5301/uijao.5000603.

[94] García-Prieto, A., et al., ''Evaluation of the efficacy of a medium cut-off dialyser and comparison with other high-flux dialysers in conventional haemodialysis and online haemodiafiltration.'' *Clin Kidney J.,* Oct. 2018, 11(5):742–746.

[95] Grooteman, M.P., et al.; ''CONTRAST Investigators. Effect of online hemodiafiltration on all-cause mortality and cardiovascular outcomes,'' *J Am Soc Nephrol.,* June 2012, 23(6), pp.1087–1096.

[96] Maduell, F., et al., ''ESHOL Study Group. High-efficiency postdilution online hemodiafiltration reduces all-cause mortality in hemodialysis patients'' *J Am Soc Nephrol.,* Feb 2013, 24(3), pp. 487–497. doi: 10.1681/ASN.2012080875. Epub 2013 Feb 14. Erratum in: J Am Soc Nephrol. 2014 May; 25(5):1130.

[97] Morena, M., et al., ''FRENCHIE Study Investigators. Treatment tolerance and patient-reported outcomes favor online hemodiafiltration compared to high-flux hemodialysis in the elderly,'' *Kidney Int.,* June 2017, 91(6):1495–1509.

[98] Ok, E., et al., ''Online Haemodiafiltration Study. Mortality and cardiovascular events in online haemodiafiltration (OL–HDF) compared with high-flux dialysis: Results from the Turkish OL–HDF Study,'' *Nephrol Dial Transplant,* Jan 2013, 28(1), pp. 192–202.

[99] Zweigart, C., 2017. Ibid.

[100] Zweigart, C., 2017. Ibid.

[101] Krause, B., et al., ''Highly selective membranes for Blood purification,'' Gambro Dialysatoren GmbH, Hechingen/Germany, Presentation abstract March 26, 2015.

[102] Zweigart, C., et al., ''Medium cut-off membranes—closer to the natural kidney removal function,'' *Int. J Artif Organs,* 2017, 40(7), pp. 328–334. DOI: 10.5301/uijao.5000603.

[103] Amyot, S.L, et al., ''Myoglobin clearance and removal during continuous venovenous hemofiltration,'' *Intensive Care Medicine,* 1999 (25), PP. 1169–1172.

[104] Friedrich J.O., et al., ''Hemofiltration compared to hemodialysis for acute kidney injury: Systematic review and meta-analysis,'' *Critical Care,* Aug 6, 2012 (16): R146.

[105] Vanholder, R., et al., ''Protein-bound uremic solutes: The forgotten toxin,'' *Kidney International.* Feb 2001, 59 (78), S266–S270.

[106] Sirich, T.L, et al., ''The Frequent Hemodialysis Network Trial Group. Limited reduction in uremic solute concentrations with increased dialysis frequency and time in the Frequent Hemodialysis Network Daily Trial.'' *Kidney Int,* May 2017, 91 (5): 1186–1192.doi:10,1016/j.kint.2016.11.002. Epub 2017 Jan 12.

[107] Kalim, S., et al., ''Extended Duration Nocturnal Hemodialysis and Changes in Plasma Metabolite Profiles,'' *Clin J Am Soc Nephrol,* Mar 7, 2018, 13(3), pp.436–444.

[108] Sirich, T.L., et al., ''The Frequent Hemodialysis Network Trial Group. Limited reduction in uremic solute concentrations with increased dialysis frequency and time in the Frequent Hemodialysis Network Daily Trial.'' *Kidney Int,* May 2017, 91 (5): 1186–1192.doi:10,1016/j.kint.2016.11.002.Epub 2017 Jan 12.

the applicant following the publication of the proposed rule.

There is significant literature on the topic of MCO membranes and high retention onset dialyzers. To evaluate this specific technology, CMS performed a literature search for published articles using the Theranova dialyzer and reviewed all articles submitted by the applicant. They are categorized according to an estimated degree of peer review. Summaries are also provided beneath each citation with disclosures also noted. On the studies with more clinically significant measures, there is more annotation added.

(d) Clinical Evidence for Claims of SCI

Below is a list of references for SCI based on evidence beginning with the highest form of evidence, peer-reviewed journals. We summarize the studies grouped by listings with the most rigorous review to those with the least rigorous review, specifically, those published in Peer-Reviewed Journals, then Review Articles and Editorials, to Posters and Abstracts, including submitted manuscripts, and ending with Incomplete Manuscripts.

Published in Peer-Reviewed Journals

• Belmouaz M, et al.[109] is a retrospective analysis of 10 patients treated with online HDF and then switched to MCO dialysis over 1 year. The authors evaluated three dialysis sessions per patient and noted that there were not significant differences between the two methods in clearance of urea, creatinine, β2-microglobulin, and myoglobin. The authors received funding support by Baxter.

• Belmouaz M, et al.[110] is a cross-over prospective study performed in France. It included 40 patients randomly assigned to receive either 3 months of medium cut-off hemodialysis (MCO–HD) followed by 3 months of high-flux HD (HF–HD), or vice versa. The primary endpoint was myoglobin reduction ratio (RR) after 3 months of MCO–HD. Secondary endpoints were the effect of MCO–HD on other middle-weight toxins and protein-bound toxins, and on parameters of nutrition, inflammation, anemia, and oxidative stress. Compared with HF–HD, MCO–HD provides higher myoglobin and other middle molecules RR and is associated with moderate hypoalbuminemia. The authors noted that the potential benefits of this strategy on long-term clinical outcomes deserve further evaluation. This study was supported by Baxter.

• Boschetti-de-Fierro A, et al.[111] is a report on in vitro testing of four prototypes for MCO membranes as compared to high-flux, high cut-off membranes, and a rat glomerular membrane model. Sieving characteristics were evaluated before and after blood contact. Authors noted that increasing pore sizes often results in loss of albumin but controlling the pore size diameter and variance results in enhanced selection for middle sized proteins. A protein layer also forms along the synthetic membrane, further restricting the loss of albumin. All authors were employed by Gambro Dialysatoren, which is part of Baxter International Inc.

• Cordeiro ISF, et al.[112] is a prospective crossover trial of 16 patients undergoing HF–HD and switched to online hemodiafiltration (olHDF) and high retention onset (HRO) HD for 4 weeks. Molarity concentrations were lowered to greater extent in olHDF and HRO–HD.

• Cozzolino M, et al.[113] is an Italian prospective, open-label, cross-over study in 20 patients which compared the Theranova 400 HD_x membrane to conventional HD, showing a non-significant trend of lower IL–1B and IL–6 levels with HD_x. Although infections were statistically more likely in the HD population, the definition of infection was vague, and most of them appeared to be with respiratory tract and fever of unknown origin. Because culture evidence was not required, the risk of bias in the categorization of infection is high (for example, upper respiratory tract infections inappropriately treated with antibiotics). The HD_x had a non-significant trend towards fewer hospitalizations. Potential risks from HD_x include an allergic reaction to polysulphone and lower serum albumin levels. The small sample size, single center disease, and short follow-up mean that the results, while promising, require substantial corroborating evidence in the form of a multi-center, blinded randomized controlled trial. The study was supported by an unrestricted grant from Baxter.

• García-Prieto A, et al.[114] is a crossover study of 18 HD patients who received online HDF for one week, then conventional HD the second week, and the use of a MCO membrane for the third week. Authors collected RR and albumin losses and noted that MCO membranes were similar in efficacy as olHDF. Both online and MCO methods had greater reduction of middle molecules. The study was conducted in Spain and authors did not declare any conflicts of interest.

• Gillerot G, et al.[115] is a research paper submitted by the applicant in which the investigators tested the role of IL–6 gene expression on 156 PD patients and its putative role in inflammation. They tested a homogeneous population of 152 from Belgium and the North of France. The investigators stated their findings substantiate the critical role played by IL–6 in the peritoneal membrane and support the hypothesis that underlying mechanisms (regulation of IL-*6* gene expression) could regulate systemic and local inflammation in association with comorbidity and uremia. However, they noted that confirmation of this hypothesis will require well-designed, adequately powered studies, in different populations and different settings. This study was focused on PD and the Theranova membrane is used in HD, so extrapolation of the IL–6 data to that modality is questionable. These studies were supported by Baxter Belgium.

• Lorenzin A, et al.[116] is a performed mathematical modeling, and through it, the authors calculated that the HRO membranes allowed for internal filtration and high convective volumes.

• Lorenzin A, et al.[117] is a paper in which the authors used semi-empirical

[109] Belmouaz M, Diolez J, Bauwens M, Duthe F, Ecotiere L, Desport E, Bridoux F. Comparison of hemodialysis with medium cut-off dialyzer and online HDF on the removal of small and middle-sized molecules. Clin Nephrol. 2018 Jan;89 (2018)(1):50–56.

[110] Belmouaz M, Bauwens M, Hauet T, Bossard V, Jamet P, Joly F,Chikhi E, Joffrion S, Gand E, Bridoux F. Comparison of the removal of uremic toxins with medium cut-off and high-flux dialysers: A randomized clinical trial. Nephrol Dial Transplant. 2020:35:328–335.

[111] Boschetti-de-Fierro A, Voigt M, Storr M, Krause B. MCO Membranes: Enhanced Selectivity in High-Flux Class. Sci. Rep. 5, 18448; doi: 10.1038/srep18448 (2015).

[112] Cordeiro ISF, Cordeiro L, Wagner CS, et al. High-Flux versus High-Retention-Onset Membranes: In vivo Small and Middle Molecules Kinetics in Convective Dialysis Modalities. Blood Purification. 2019 Jul 30:1–8.

[113] Cozzolino M. Magagnoli L, Ciceri P, Conte F, Galassi A. Effects of a medium cut-off (Theranova) dialyser on haemodialysis patients: A prospective, cross-over study. Clinical Kidney Journal, 2019, 1–8.

[114] García-Prieto A,Vega A, Linares T, Abad S, Macías N, Aragoncillo I, Torres E, Hernández A, Barbieri D, Luño J. Evaluation of the efficacy of a medium cut-off dialyser and comparison with other high-flux dialysers in conventional haemodialysis and online haemodiafiltration. Clin Kidney J. 2018 Oct;11(5):742–746.

[115] Gillerot G, Goffin E, Michel C, Evenepoel,P, Van Biesen W, TIntillier M, Stenvinkel P, Heimburger O, Lindholm B, Nordfors L, Robert A, Devuyst O. Genetic and Clinical Factors Influence the Baseline Permeability of the Peritoneal Membrane. Kid Int. 2005; 76: 2477–2487.

[116] Lorenzin A, Neri M, Clark WR, et al. Ronco C (ed): Expanded Hemodialysis—Innovative Clinical Approach in Dialysis. Contrib Nephrol. Basel, Karger, 2017, vol 191, pp 127–141.

[117] Lorenzin A, Neri M, Clark WR, Garzotto F, Brendolan A, Nalesso F, Marchionna N, Zanella M,

Continued

methods to estimate convective volumes for Theranova 400 and Theranova 500 under standard 4-hour HD conditions. Using their ''most complex'' mathematical model that incorporated gradients and blood changes along the dialyzer length, authors estimated internal filtration rates of 300ml/min and 400 ml/min for both hemodialyzers.

• Lorenzin A, et al.[118] is an *in vitro* test of Theranova 400 and 500 at zero net ultrafiltration. Albumin macro-aggregates were labeled with Technetium-99m (99mTc) to assess cross filtration through the length of the filter. Using a gamma camera, local cross filtration and internal filtration were calculated. Authors noted that the MCO membrane allowed for clearance of medium-large molecular weight solutes (~11 KDa) and retention of more albumin without requiring special equipment. The authors had no disclosures.

• Macías N, et al.[119] is a prospective study of 14 patients on maintenance olHDF. Patients underwent a midweek dialysis session with the Theranova-500 machine under their usual dialysis conditions. Researchers measured the presence of uremic toxins at various molecular weights pre-dialysis, and post-dialysis. Pressures at the inlet and outlet of dialyzer compartments were also measured to estimate direct filtration and back filtration volumes. Researchers used semi-empirical methods to determine that diffusive clearance was more prominent than convective transport (which requires higher volumes). No funding or financial contribution was supplied. Membranes, monitors, and laboratory tests were those routinely used in the dialysis unit.

• Reque J, et al.[120] is a prospective study of eight patients who either underwent olHDF or underwent HDx with Theranova 500 for 24 sessions. After a 1-week washout with HF–HD, all patients crossed over to the alternative method. Laboratory values were obtained before and after each session, specifically of urea, creatinine, phosphorous, beta2-microglobulin, myoglobin, and prolactin. The urea and beta2-microglobulin reduction ratios were the same but HDx demonstrated higher RR of myoglobin (60 percent compared to 35 percent in HDF). The authors had no disclosures.

Review Articles/Editorials

This is the second grouping in the list of evidence for SCI from most compelling to least compelling. We summarize the studies the applicant provided as follows:

• Caramelo C, et al.[121] is an article that reviews the clinical and pathophysiological characteristics of anemia in this context. Particular emphasis has been placed on cellular and molecular regulatory mechanisms, and their implications for treatment. The applicant referenced the review article's language on hepcidin, because it is considered the homeostatic regulator of iron in its intestinal absorption, its recycling by macrophages and its mobilization from liver stores. Its transcription is markedly induced in inflammatory processes, especially by cytokines like IL–6.

• Florens N, et al.[122] is a review article included in Baxter's application. It summarizes feedback from the first routine use of HD_x therapy under real-life conditions in European facilities. The authors reported no adverse event after 5,191 HD_x treatments, and opined that patients suffering from itching, restless legs syndrome, persistent asthenia or malnourishment could benefit from HD_x therapy. While they discussed the promising applications in which HD_x could be valuable (myeloma, rhabdomyolysis or cardiovascular diseases), the message is mitigated by reminding why and how prudence should be taken in the design of future HD_x studies, particularly with poor de-aeration of the filter in automatic mode and manual intervention required to prime the membrane. Some patients required more anti-coagulation using the Theranova membrane. In addition, patients were aware of the use of the Theranova device because of lack of logo removal. The authors noted that although promising, the clinical evidence is incomplete. Both authors received a grant Investigator Initiated research for the evaluation of HD_x in clinical practice and one performed occasional lectures for Baxter.

• Wolley M, et al.[123] is a clinical review article that recognizes that advances in dialysis technology do not always improve patient outcomes, and it reviews the clinical relevance regarding the removal of LMMs, particularly those involved in chronic inflammation, atherosclerosis, structural heart disease, and secondary immunodeficiency. The authors noted that single-center safety and efficacy studies have identified that use of these membranes in maintenance dialysis populations is associated with limited loss of albumin and increased clearance of large middle molecules. When the review was published in 2018, the authors noted that larger, robustly conducted, multicenter studies were evaluating these findings. They concluded that after completion of these safety and efficacy studies, the perceived clinical benefits of providing clearance of LMMs must be assessed in rigorously conducted, randomized clinical studies. One of the authors received research funding from Baxter and participated on advisory boards and speaker bureaus for Baxter.

• Zweigart C, et al.[124] is an editorial review submitted by the applicant on MCOs, which was generally favorable with regard to high quality and good performance. All of the authors are employees of the Gambro Dialysatoren GmbH, Hechingen (Germany) or Gambro Lundia AG. Gambro AB (including all direct and indirect subsidiaries) is now part of Baxter International Inc.

Posters and Abstracts

This is the third grouping in the list of evidence for SCI from most compelling to least compelling. We summarize the poster sessions and abstracts, including submitted manuscripts which the applicant provided as follows:

• Belmouaz M, et al.[125] is a randomized open label crossover study in which 46 patients underwent MCO–HD and HF–H). MCO–HD had higher medium RRs of myoglobin and beta-2 microglobulin and increased albumin

Sartori M, Fiore GB, Ronco C. Modeling of Internal Filtration in Theranova Hemodialyzers. Contrib Nephrol. 2017;191:127–141.

[118] Lorenzin A, Neri M, Lupi A, Todesco M, Santimaria M, Alghisi A, Brendolan A, Ronco C. Quantification of Internal Filtration in Hollow Fiber Hemodialyzers with Medium Cut-Off Membrane. Blood Purif. 2018;46(3):196–204.

[119] Macías N, Vega A, Abad S, Aragoncillo I, García-Prieto AM, Santos A, Torres E, Luño J. Middle molecule elimination in expanded haemodialysis: Only convective transport? Clin Kidney J. 2018 Dec 15;12(3):447–455.

[120] Reque J, Pérez Alba A, Panizo N, Sánchez-Canel JJ, Pascual MJ, Pons Prades R. Is Expanded Hemodialysis an Option to Online Hemodiafiltration for Small- and Middle-Sized Molecules Clearance? Blood Purif. 2019;47(1–3):126–131.

[121] Caramelo C, Just S, Gil P. Anemia in Heart Failure: Pathophysiology, Pathogenesis, Treatment and Incognitae. Rev Esp Cardiol. 2007; 60(8): 848–860.

[122] Florens N, Juillard L. ''Expanded Haemodialysis: News from the Field,'' Nephrol Dial Transplant, 2018; 33: iii48–iii52.

[123] Wolley M, Jardin M, Hutchinson, C. ''Exploring the Clinical Relevance of Providing Increased Removal of Large Middle Molecules,'' Cli, J Am Soc Nephrol 2018;13: 805–813.

[124] Zweigart C, Boschetti-de-Fierro A, Hulko M, Nilsson L–G, Beck W, Storr M, Krause B. Medium Cut-Off Membranes—Closer to the Natural Kidney Removal Function. Int j Artif Organs. 2017; 40(7); 328–334.

[125] Belmouaz M, Bauwens M, Bouteau I, Thierry A, Ecotiere L, Bridoux F. Comparison of the Removal of Uremic Toxins with Medium Cut-Off and High-Flux Dialyzers: A Randomized Clinical Trial. TH–PO348, 2018.

loss compared to HF–HD. The authors received funding support by Baxter.

• Boschetti-de-Fierro A, et al.[126] is a poster in which the investigators assessed the performance of the MCO devices in simulated HD and HDF treatments. The applicant's submission of the material presented in this poster was incomplete regarding date and location of the poster session. This study was funded by Baxter.

• Kharbanda K, et al.[127] is a randomized study funded by Baxter Healthcare and the National Institute for Health Research which compared HDF with HD_x and suggested an improved recovery time with HD_x. The study showed lower levels of endothelial cell microvesicles in HD_x. However, the study did not have comparable baseline recovery times (for example, 41 percent with < 2 hours with HD_x versus 35 percent with HDF) and the authors performed a per-protocol rather than an intention to treat analysis, exacerbating bias in the study.

• Kirsch AH, et al.[128] is a poster that summarizes a two pilot randomized controlled prospective open-label crossover studies, in which 39 HD patients underwent treatment with MCO membranes, a HFD, and HDF. The authors concluded that MCO–HD removed middle molecules (free light chain) more effectively than high-flux and high-volume HDF. However, the authors noted that there are several limitations of the study. First, compared to the control dialyzers used, the experimental membranes used were different, less tight membranes. Second, the study design was confined to only one single treatment with each dialyzer for each patient and the study did not examine the long term effects of such membranes on serum levels of middle molecules and albumin. The authors conclude that future studies should assess whether the performance of MCO–HD improves clinical outcomes. The study was conducted in Germany and funded by Baxter, and the conflicts of interest statement in the paper lists three of the ten authors as employees of Baxter.

• Bunch, A, et al.[129] is a multicenter prospective study in prevalent HD patients, older than 18 years old; enrolled from September 1 to November 30, 2017, and converted to HD_x using Theranova 400. The investigators found an initial small decrease in serum albumin level, which stabilized and was within the normal range per their Bogata, Columbia laboratory references. Although Table 1 and Table 2 were cited in the abstract, both were missing. Dialysis performance adequacy (Kt/V) was achieved. No clinically significant differences in laboratory values at 6 months with November 30 of 2017, and converted to HD_x using Theranova 400 (3 sessions per week, 4 hours per session, same heparin dose). The lead author has been listed as the medical director of Renal Therapy Services, owned by Baxter, in Bogota, Columbia.

• Cantaluppi V, et al.[130] is a multicentric observational study of 6 months follow-up. American Society of Nephrology (ASN) Week, 2018, Abstract, Thu-PO357. This multicenter (Italy) study evaluated 41 HD patients comparing standard HD molecular levels versus HD_x and found a significant decrease in urea, beta-2-microglobulin, and free light chains. The study did not evaluate clinical outcomes.

• Cantaluppi V, et al.[131] is an abstract submitted by the applicant reporting on a study where 41 HD patients (age 67,6±13,4) in standard high flux HD were shifted to HDx using Theranova 400 (1.7 m2, Baxter). Each patient was studied at baseline HD (T0), 3 months (T3) and 6 months (T6) after HD_x, after which they were evaluated the following pre-dialysis parameters: Urea, Creatinine, Phosphate, Beta2-microglobulin, Myoglobin, Free Light Chains, Hemoglobin, Albumin and CRP. For in vitro studies, T0 and T6 plasma were used to evaluate neutrophil activation (ROS generation, apoptosis, adhesion) and endothelial dysfunction/senescence. The investigators concluded that HD_x therapy provided high removal of different LMMs, leading to a significant reduction of molecules involved in uremia-associated inflammation and organ dysfunction (in particular Free Light Chains kappa and lambda). Long-term studies with a larger sample size are needed to evaluate the clinical impact of HD_x.

• Cozzolino, M.[132] is an abstract of a pilot study with 20 prevalent HD patients studied for six months in two dialysis treatments: One MCO (Theranova) dialyzer and one high-flux dialyzer. The author claimed the pilot study shows the Theranova dialyzer has a good tolerance profile and reduces the cumulative number of infections in HD patients. The study was funded by an unrestricted grant from Baxter.

• Gallo M.[133] is a single cohort study in Italy which compared HDx to baseline HD treatments in 15 patients and showed no difference in uremic toxins, though there was a change in ESA dose.

• Gernone G, et al.[134] is a single cohort study in Italy which investigated 14 patients using Theranova with baseline HD and showed no statistical change in outcomes, clearance, or quality of life.

• Jung JH, et al.[135] is a study that was questionably designed since they chose young, well-nourished patients at the start of the study, which made it difficult to analyze the comparison of the two groups at various points in time. This observational study of 42 Korean patients comparing HD to HD_x showed no comparative difference between the two groups in any markers.

• Krishnasamy R, and Hutchinson C.[136] is an abstract submitted by the

[126] Boschetti-de-Fierro A, Voigt M, Huiko M, Krause B. MCO Dialyzers: Enhanced Selectivity in High-Flux. Gambro Dialysatoren GmbH, Research and Development, Hechingen, Germany, Poster No. SAT–481 (Baxter).

[127] Kharbanda K, Herring A, Wilkinson F, Alexander Y, Mitra S. A Randomised Study Investigating the Effect of Medium Cut-Off Haemodialysis on Markers of Vascular Health Compared with On-Line Haemodiafiltration (MoDal Study). Manchester Metropolitan University. 2019

[128] Kirsch AH, Lyko R, Nilsson LG., et al. Performance of hemodialysis with novel medium cut-off dialyzers. Nephrol Dial Transplant 2017; 32: 165–172.

[129] Bunch A., Nilsson L, Vesga J, Ardila F, Zuniga E, Alarcon J. ''Long-Term Effects of Expanded Hemodialysis (HD_x) on Clinical and Laboratory Parameters in a Large Cohort of Dialysis Patients'' ASN 2018 Kidney Week Abstract FR–P0766.

[130] Cantaluppi V, Donati G, Lacquaniti A, Cosa F, Gernone G, Marengo M, Teatii U Removal of large-middle molecules on expanded hemodialysis (HDx): A multicentric observational study of 6 months follow-up. ASN Week, 2018, Abstract, Thu-PO357.

[131] Cantaluppi V, Marengo M, Allessandro Q, Berto M, Donati G, Antonio L, Cosa F, Gernone G, Teatini U, Migliori M, Panichi V. Removal of Large-Middle Molecules, Inhibition of Neutrophil Activation and Modulation of Inflammation-Related Endothelial Dysfunction During Expanded Hemodialysis (HDx), Nephrol Dial Transplantation, June 2019, 34, Issue Supplement_1. gfz096.FO048, *https://doi.org/10.1093/ndt/gfz096.FO048.*

[132] ''Effects of Medium Cut-Off (Theranova) Dialyzer on Hemodialysis Patients: A Prospective Cross-Over Study [Abstract].'' J Am Soc Nephrol, 29. 2018, pp. 616–617.

[133] Gallo M. The Real-Life study on expanded hemodialysis (HD_x): 9 months experience of a single hemodialysis unit. Nephrol Dial Transplantation and Transplantation, June 2019, ERA EDTA Abstract. FP539.

[134] Gernone G, Montemurro M, Capurso D, Colucci G., Dell'Anna D, Deltomaso F, LaRosa R, La Volpe M, Partipilo F., Pepe V, Ripa E. Mid-term evaluation of the new medium cut-off filter (Theranova) on removal efficiency and quality of life. Nephrology and Transplantation, Abstract. SP489.

[135] Jung JH, Song JH, Ahn S–H. A 6-month study on the efficacy of hemodialysis therapy using dialyzers with medium cut-off membranes in Asian patients with end-stage renal disease. Nephrol Dial Transplantation, June 2019, 84 Issues Supplement-1, gfz103.SP487, *https://doi.org/10.1093/ndt/gfz103.SP487.*

[136] Krishnasamy R, and Hutchinson C. Trial Evaluating Mid Cut-Off Value Membrane Clearance

Continued

applicant from this single-arm, multi-center study with 92 Australian/New Zealand patients. The study examined the safety and efficacy and patient-centered outcomes of MCO dialyzer use in chronic HD patients over 6 months. The investigators concluded that there was a small but acceptable reduction in serum albumin in regular HD using the MCO dialyzer. However, the figures were not included in the abstract sent by the applicant for review by CMS. The investigator noted that future randomized controlled trials should assess the impact of the MCO dialyzer on clinical and long-term patient-centered outcomes.

• Krause B, et al.[137] is a description of membrane manufacturing utilizing hollow fiber technology.

• Weiner DE, et al.[138] included two items for this U.S. based study at a large academic medical center. The first was the ASN 2019 Scientific Congress abstract and the second was a copy of the poster session at the ASN annual meeting in 2019. This open label randomized controlled trial in 172 patients who underwent 24 weeks of Theranova 400 MCO dialyzer compared to a high flux dialyzer showed a potential decrease in hospitalizations with HD_X, but the authors did not produce statistical tests of significance. While this was a randomized control trial (RCT), covariates were not well-balanced, including substantially more patients with diabetes in the conventional HD arm. The study showed lower lambda free light chains in HD_X compared to high flux HD. Albumin levels were maintained in both. The presenters concluded that larger studies of longer duration are needed to assess if better larger molecule clearance is associated with improvements in clinical outcomes, including vascular disease, quality of life, and mortality. The authors received commercial support from Baxter.

• Alarcon J, et al.[139] describes a study over 12 months in which 992 patients from 12 renal clinics were followed after switching from high-flux HD to HD_X. The authors assessed many patient quality of life outcomes using the short form kidney disease quality of life (KDQoL–SF36), dialysis symptom index (DSI) and prevalence of restless leg syndrome (RLS) and found modest reductions in DSI severity scores, increases in KDQoL–SF36 scores in some domains (but unchanged in the mental and physical domains), and reduced prevalence of restless leg syndrome. Notably, the authors did not provide a control group. Also, the authors performed a large number of statistical tests without adjustment, further increasing the risk of Type 1 error. The study was supported by Renal Therapy Services-Columbia, owned by Baxter. Five of the eight authors are employees of Renal Therapy Services. One author is a full-time employee of Baxter and has a patent pending for RLS medication.

• Ariza J, et al.[140] is a manuscript that was provided by the applicant. Cost estimates were extrapolated using an observational design, which suggested lower hospital days (but not hospitalizations) and lower medication use in the HD_X. However, the lack of randomization makes this study difficult to evaluate. Furthermore, the authors did not show any difference in costs between HD_X and HD. The study was funded by Baxter.

• Penny JD, et al.[141] is a manuscript in submission that was included by the applicant. It is a single case-study of a HD patient with pruritis and extreme levels of tissue sodium. Both responded to HD_X therapy. The authors acknowledged that further robust clinical exploration is required.

• Sanabria RM, et al.[142] is manuscript provided by the applicant and has not been published. The observational study followed 81 patients receiving high-flux HD for 1 year who subsequently switched to HD_X for 1 year. While there was a significant reduction in number of hospital days (but no change in hospitalization rate) and medication use, findings were limited by the lack of a control group. The shortening of hospital stays could be attributed to a systematic change in admission practice patterns, rather than HD_X. Furthermore, Kt/V was higher in the HD_X group, but the authors did not standardize dialysis dosing, making it difficult to attribute effects to HD_X or to other causes of increased dialysis adequacy. Hemoglobin levels, albumin, hsCRP were not statistically different in the two arms. All investigators are employees of RTS Ltd, Columbia, an affiliate of Baxter Healthcare. The study was supported by Renal Therapy Services-Columbia, an independent entity owned by Baxter International, Inc.

Incomplete Manuscripts

This is the fourth and final grouping in the list of evidence for SCI from most compelling to least compelling. We summarize the incomplete manuscripts which the applicant provided as follows:

• Bolton S, et al.[143] is a manuscript provided by the applicant and is unfinished. It describes a crossover study of patients previously treated with high-flux HD and switched to Theranova. Patient reported outcome measures (PROMs) suggested decreased self-reported dialysis recovery time and symptom burden, especially at 6 months. However, regression to the mean appeared common, and there was no control group.

• Lim J, et al.[144] is a manuscript provided by the applicant, reporting a randomized trial comparing MCO to high-flux HD, with 50 patients undergoing 12 weeks of treatment in Korea. The study was small, and the authors performed a large number of statistical tests comparing quality-of-life outcomes, with only a couple statistically significant. Without adjusting p-values for the number of statistical test, the risk for Type 1 error is large and not unexpected. A second trial suggested lower medication doses, but again results were statistically significant only for a few of the parameters of interest. The study is small and requires replication at additional centers to confirm results.

• Lim J–H, et al.[145] is a manuscript provided by the applicant, reporting a

of Albumin and Light Chains in Hemodialysis Patients (REMOVAL–HD): A Safety and Efficacy Study. Oct. 2018 ASN Scientific Congress Abstract TH–PO363.

[137] Krause B, Boschetti-de-Fierro A, Dutczak S, Zweigart C. Highly Selective Membranes for Blood Purification. Jahrestreffen der Fachgruppen ''Fluidverfahrenstechnik'' und ''Membrantechnik'' 26 Mar 2015.

[138] Weiner DE, Falzon L, Beck W, Xiao M, Tran H, Bernardo AA. Efficacy and Safety of Expanded Hemodialysis Enabled by a Medium Cut-Off Membrane: A Randomized Control Trial. FR–PO 488, ASN 2019.

[139] Alarcon J, Bunch A, Ardila F, Zuniga E, Vesga J, Rivera A, Sanchez R, Sanabria M. Real world evidence on the impact of expanded hemodialysis (HD_X) therapy on Patient Reported Outcomes (PROs): CPREXH Registry (in submission).

[140] Ariza J., Walton SM, Sanabria M, Vega J, Suarez A, Rivera A. An Initial Evaluation of the Potential Cost Impact and Cost Effectiveness of Expanded Hemodialysis (in submission).

[141] Penny JD, Salerno F, Akbari A, McIntyre, C. ''Pruritis-Is There a Salty Truth?'' (in submission). The applicant included a manuscript in submission.

[142] Sanabria RM,Vesga JI, Ariza J, Sanchez R, Suarez A, Bernardo A, Rivera A. Expanded Hemodialysis and its effects on hospitalization and medication usage: An exploratory study. (in submission).

[143] Bolton S, Gair S, Metthews M, Stewart L, McCullagh N, A 1-year routine assessment of patient-reported symptom burden after implementing expanded hemodialysis, 2019. (in process).

[144] Lim J, Park Y, Yook J, Choi S, Jung H, Choi J, Park S, Kim C, Kim Y, Cho J. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality-of-life outcomes in maintenance hemodialysis patients. (in submission).

[145] Lim J–H, Yook J–M, Choi S–Y, Jung H–Y, Choi, J–Y, Park S–H, Kim C–D, Kim Y–L, Cho H–

randomized trial comparing MCO to high-flux HD, with 50 patients undergoing 12 weeks of treatment in Korea. Its purpose was to evaluate the effects of ESA resistance of HD using a MCO dialyzer. The number of registered patients was small and the study duration not long enough to assess definite results. Also, the study was not blinded to clinicians, which may have affected the ESA and iron supplementation prescriptions. Additional studies need to be performed to assess clinical outcomes.

(e) CMS Comments on the Baxter Application

In the CY 2021 ESRD PPS proposed rule (85 FR 42175), CMS discussed the specific concerns regarding the evidence submitted for proof of eligibility via the SCI criteria. While Theranova represents a unique technology, CMS noted that the current evidence supporting SCI is lacking but that other evidence may be forthcoming during the comment period. CMS believes it's too early to tell if the patient-recorded outcomes, such as fewer cardiovascular events, are significant because of the small numbers in the studies. Specifically, a study for infection was cited with an N=20; another had an N=10. Also, the definition of the infection was vague. Although hospitalization rates are discussed in the articles, the cause of the hospitalization was unknown. Patient laboratory results should be correlated with patient-reported results. In the submitted articles, the studies are all open-label and observational, with tenuous findings; alternative approaches could include larger studies focused on the U.S. dialysis population's patient health outcomes with patients blinded in these studies.

The background information provided by the applicant and researched by the group is conflicting. This may be due to the variation in the location of the studies, including Columbia, France, Belgium, England, Ireland, Australia, New Zealand, and Korea. CMS suggested a meta-analysis be done, along with the heterogeneity of dialysis care in those countries as compared to the care received by the Medicare population in the U.S.

In the CY 2021 ESRD PPS proposed rule (85 FR 42176), CMS stated that while HD_X appears to be a promising technology, the current state of evidence insufficiently demonstrates SCI in Medicare patients undergoing dialysis, but that additional evidence may be forthcoming in the comment period. In general, the dialyzer appears to have improved middle molecule clearance. While observational studies show an association between high levels of middle molecules and poor outcomes, these correlations do not prove causation. For instance, a growing body of evidence suggests that protein-bound solutes such as indoxyl sulfate and p-cresol sulfate could be responsible for the uremic syndrome. Conventional HD, HDF, and HD_X do not effectively clear protein-bound toxins.

In the CY 2021 ESRD PPS proposed rule (85 FR 42176), CMS provided a summary of the current body of evidence:

- Theranova more effectively removes middle molecules compared to conventional dialysis with high-flux membranes. These include molecules that have varying degrees of plausible toxicity (for example, beta 2 microglobulin to cytokines to endothelial proteins). Because nephrologists have not identified the putative uremic toxin, it is not certain that clearance of these toxins will lead to improved clinical outcomes.
- Although small before and after studies suggest potential clinical benefits from MCO dialyzer membranes compared with conventional HD via high-flux membranes, such as reduced infection, improved itching and restless legs, and shorter recovery time from dialysis, these studies are mostly observational, small in nature, with a high potential for bias. A large, multi-center trial would be necessary to prove substantial benefit from HD_X over conventional HD.
- Several small studies suggest that MCO dialyzer membranes are comparable to HDF in removal of middle molecules, but online HDF is not generally available in the U.S. Furthermore, online HDF has not consistently shown to improve health outcomes relative to conventional HD with high-flux membranes.
- There may be increased removal of albumin with MCO membranes compared to conventional high-flux dialysis, which could have negative health consequences.
- A large randomized controlled clinical trial did not demonstrate clinical benefits from removing larger solutes, including middle molecules, but the study did not examine newer technologies such as hemodiafiltration which are more efficient in removing those. This negative study provides reason to be somewhat skeptical about the benefits of HD_X over HD.
- Following the FDA-requested 6-month clinical study to validate efficacy of large toxin removal and safety, the applicant stated that it anticipates FDA marketing approval in May 2020. However, we note that, per the application, safety is defined in part by albumin loss. At this time we do not believe the clinical trials included safety and efficacy studies for the large middle molecules the applicant asserts to be the cause of inflammation. Therefore, the perceived clinical benefits of providing clearance of those large middle molecules were not assessed in rigorously conducted, randomized clinical studies.

As stated previously, at the time of the CY 2021 ESRD PPS proposed rule there was concern about the sufficiency of the evidence available for Theranova demonstrating a clear clinical benefit for Medicare dialysis patients. However, we noted that additional evidence could be forthcoming in the comment period, and invited public comment as to whether Theranova meets the TPNIES SCI criteria.

The collective comments and our response are set forth below.

Comment: The applicant provided information and a meta-analysis that duplicated information provided in the CY 2021 ESRD PPS proposed rule. Several physician commenters provided comments in support of the research. The commenters' disclosures in their publications noted financial support from the applicant. The commenters stated that they believed that Theranova meets the criteria set forth in TPNIES for SCI over the existing standard of care. The commenters urged CMS to reconsider the data, and review such data in its combined totality rather than focusing on each study in isolation. The commenters asserted that existing data supported improved clinical outcomes with the removal of large middle molecules, including Interleukin-6, YKL–40, Alpha-1 microglobulin, and Lambda Free Light Chains (FLC), which have been associated with inflammation, cardiovascular events, and other dialysis-related comorbidities.

A physician commenter stated that changing over to Theranova-based HD from conventional high-flux HD might partially restore some of the benefits of residual renal function to patients. The commenter stated that these larger molecules are removed poorly, if at all, by conventional high-flux HD, resulting in plasma levels that are many times above the normal value. The commenter stated that it is known that clinical outcomes are improved in dialysis patients with even small amounts of residual renal function, and that there

H. Novel Medium Cut-Off Dialyzer Improves Erythropoiesis Stimulating Agent Resistance in Maintenance Hemodialysis Patients: A Randomized Control Trial. (in submission).

are multiple reasons for this, one likely being the failure of current methods of dialysis to remove large middle molecules. The commenter also stated that high plasma levels of these and similar molecules have been associated with increased mortality, inflammation and cardiovascular disease.

Another physician commenter stated that based on the clinical data presented in the CY 2021 ESRD PPS proposed rule, the commenter believed that Theranova therapy represented a substantial clinical improvement in treatment for Medicare beneficiaries on dialysis. The commenter studied the impact of Theranova on endothelial cells and noted that it had a positive impact on the process of atherosclerosis formation. The commenter also found that the effects of Theranova on vascular calcification in vitro was significantly reduced after Theranova therapy, compared to other high-flux dialyzers, and that cell death was significantly lower in the Theranova group.

A physician commenter asserted that accumulated or increased levels of Interleukin-6 may contribute to the chronic inflammation state of ESRD patients, thereby increasing the risk of chronic vascular disease and bacterial infections. Another physician commenter stated that accumulated or increased levels of Interleukin-6 increased the risk of protein energy wasting, has been associated with anemia in HD patients, and has been identified as a principal driver of early vascular aging with calcification. The commenters asserted that YKL–40 has been linked to atherosclerosis, rheumatologic diseases, arterial stiffness, stroke, mortality in type 2 diabetes, that it adds to vascular inflammation risk prediction for all-cause and cardiovascular mortality, and is associated with cardiovascular events in HD patients. The commenters also noted that the removal of large middle molecules like Alpha-1microglobulin, may alleviate insomnia, pruritus, irritability, restless leg syndrome, anemia, and osteoarticular pain. Further, the commenters noted that removal of FLCs, which is associated with non-traditional cardiovascular risk factors, including markers of inflammation, could reduce mortality risk in persons with ESRD.

The commenters noted that current dialytic therapies, due to current design and limited by membrane permeability, have limited capacity to remove the expanded range of uremic toxins, including the spectrum of large middle molecules that Theranova, as demonstrated by the collective evidence to date, removes. The commenters therefore stated treatment with Theranova results in substantial clinical improvement over current HD therapies treating renal failure.

Several physician commenters asserted, in reliance on research cited as part of the primary TPNIES application, that important clinical data has been accumulated internationally during the past 5 years demonstrating that use of the Theranova dialysis system results in clinically meaningful improvement outcomes, including patient quality of life measures, such as reduced symptom burden, decreased restless leg syndrome, decreased itching, and improved physical function. In addition, the commenters noted more rapid recovery after a dialysis session, with preliminary data suggesting that all-cause hospitalization length of stay might be reduced with Theranova versus conventional HD, and that the need for ESA therapy might be reduced.

Another physician commenter stated that the Theranova dialyzer offers the improved spectrum of larger molecule clearance associated with hemodiafiltration, but only requires a standard HD machine, and represents the type of innovation and improvement long lacking for Medicare beneficiaries on HD and potentially meeting the standard for substantial clinical improvement under TPNIES.

One commenter, a nephrologist, noted that they conducted a randomized controlled trial of Theranova versus high-flux dialyzer in maintenance HD patients to investigate the effect of Theranova on the removal of middle molecules, utilizing a total of 50 patients randomized to either Theranova or a high flux group, and stated that the Theranova dialyzer displayed better removal of κFLC and λFLC compared with the high-flux dialyzer. The commenter indicated that the results were consistent with those of other studies and asserted that taken together, Theranova dialyzer showed a greater removal of larger middle molecules than high-flux dialyzer and could decrease their blood concentrations.

The study also evaluated improved quality of life in those patients, and noted that the Theranova group showed better scores in physical functioning and role physical domains in physical component domain at 12 weeks. The commenter stated that this suggested that the Theranova dialyzer may improve patient-reported outcomes, particularly physical components and uremic pruritus in HD patients.

The study also evaluated the effect of improving ESA resistance, and the commenter hypothesized that Theranova could improve the ESA resistance because it has better removal of large middle molecules than hemodiafiltration. The commenter stated that the changes might be associated with a greater reduction in TNF-α and lower serum TNF-α level in Theranova compared to the high-flux group, and that Theranova has potential to reduce ESA dose with further study possibly proving the cost-effectiveness of Theranova for ESA use. The commenter concluded that Theranova achieved more improvement in ESA resistance than the high-flux dialyzer, removed more quantity of the inflammatory cytokine such as TNF-α than the high-flux dialyzer, potentially influencing the iron metabolism.

The commenter stated that although they did not yet have evidence that Theranova could improve the survival rate of HD patients, they noted that ongoing multicenter trials might reveal the effect of Theranova on the survival of HD patients, and expressed hope that before this, U.S. patients could have a chance to use Theranova, which has proven benefits without any serious side effects.

Another physician commenter stated that Theranova offers SCI because the commenter is able to switch patients progressively from hemodiafiltration to HD. The commenter has also observed clinical improvement in their patients, especially the impact in recovery time and nutrition, even those treated for a long period by hemodiafiltration. The commenter stated that evidence for improved removal of large uremic toxins, without the burden of external fluid reinjection such as in hemodiafiltration may occur immediately without the burden of extensive training for physicians and staff.

Two commenters reiterated the CY 2021 ESRD PPS proposed rule's explanation that, compared to the general population, patients with ESRD who receive dialysis are at an increased risk of death, commonly suffer from uremic symptoms such as itching, restless legs, and malnutrition, are at increased infection risk, and dialyze with standard high-flux dialyzers that focus entirely on removing smaller uremic toxins. The commenters stated that the removal of large middle molecules will address many of these concerns and is associated with decreased hospitalization length and the number of hospitalizations, a reduced need for certain medications, reduced inflammation and infection, improved recovery times, and improved quality of life. The commenters urged CMS to consider the totality of the evidence

combined, rather than focusing on each study in isolation, and stated their belief that the clinical data supports Theranova's application and claims of SCI.

Several beneficiary commenters commended CMS's efforts in promoting dialysis innovation through the TPNIES policy. We also received comments from other stakeholders that commended CMS on promoting dialysis innovation. Those commenters and others, including several physicians, stated that approval of applications for the TPNIES would improve treatment choices for patients and address systemic barriers that may limit access to Medicare beneficiaries suffering with kidney failure.

Physician commenters expressed concern that CMS did not address the COVID–19 pandemic, and strongly support efforts to expand access to new dialysis products, particularly during the pandemic. The physician commenters stated that COVID–19 may provoke a ''cytokine storm,'' with cytokines leading to complications, and that Theranova may reduce the presence of cytokines. The commenters noted that, as a result, a clinical guideline in Italy recommends Theranova in managing COVID–19 positive patients undergoing HD to reduce the severity of a cytokine storm. One physician commenter stated that since increased persistent inflammation inhibits immunity and affects responses to infections, it is logical to aim for a reduction of inflammatory drivers during HD in a patient group at high risk of adverse outcome during COVID–19 infection. The commenters urged CMS to consider this information in light of the COVID–19 pandemic.

Another commenter stated that as we learn more about COVID–19, there are indications that Theranova may offer a unique clinical benefit to COVID–19-positive patients, and urged CMS to take into account the challenging environment and expand access to new dialysis products, especially during the pandemic.

Several physician commenters noted that the Theranova system allows for removal of large uremic toxins, without spilling clinically important amounts of albumin, because the membrane pores vary less in size than many other membranes, and because of relatively high internal resistance, leading to increased within-dialyzer convective removal. One physician commented that one of the major concerns with Theranova is the risk of albumin loss and the removal of essential proteins by a more permeable membrane. The commenter stated they compared laboratory data including serum albumin, and as a result, laboratory data such as hemoglobin, creatinine, phosphate, and lipid, and dialysis adequacy were not different at baseline and 12 weeks between the two groups. The commenter found that the serum albumin concentration after 3 months of using Theranova dialyzer decreased by a mean of 0.13 ± 0.23 mg/dL from baseline, and that the serum albumin concentrations did not differ between Theranova and high flux dialyzers. The commenter concluded that the Theranova dialyzer has a non-significant effect on the serum albumin concentration over 12 weeks of treatment. The commenter asserted that their conclusion was supported by long-term studies. In their opinion, the decrease in serum albumin is more prominent in the early period of Theranova dialyzer use. However, when examined within the 1-year period, the change is minor and without significance. The commenter added that regarding other adverse events in their study, there were no serious adverse events including cardiovascular events, patient death, or a decline of blood pressure that required dialyzer changes throughout the 12 weeks.

One physician commenter claimed that, in their experience, albumin levels stay stable over many months with Theranova. The commenter further noted that during their trials, patients tolerated Theranova very well, many reported an improved quality of life, and the commenter indicated no knowledge of relevant side effects.

Several patient commenters expressed varied sentiments regarding the TPNIES policy. One commenter stated that home dialysis permitted the commenter to work until retirement. Another commenter, self-identified as having been on dialysis for nearly a decade, encouraged support for dialysis patients. Other commenters, both recent dialysis patients and those with kidney failure and other related illness, expressed general support for innovations, options and services to support treatment. One commenter, a decade's long beneficiary, stated the commenter had been diagnosed with ESRD since early childhood, has had numerous kidney transplants and has been on home and in-center dialysis. This commenter indicated that they proactively sought out the best care, machines and innovations the market offered, since they felt most dialysis patients are not offered such options as they are not promoted or known. The commenter stated that they supported advancements to information, technology and innovations to improve the care of dialysis beneficiaries, as in their view the current system minimally offered adequate care, which was not enough, and which commenter stated ESRD patients needed to offer them a higher quality of life care. One commenter, whose significant other is on PD dialysis at home, asked for continued support of new innovations for the thousands of dialysis beneficiaries who rely on dialysis to live, and stated that the cycler machines were old, refurbished multiple times and that they had to replace machines several due to noise or other issues.

An LDO commenter indicated that they performed a systematic review of published literature in preparation for a potential meta-analysis on hospital admissions and patient-reported outcomes, including quality of life, comparing patients dialyzed with Theranova and high flux dialyzers. The commenter stated that 45 relevant publications were identified for potential inclusion in the meta-analysis, but 40 of those publications were excluded due to the following reasons: No availability in English or not conducted in HD patients (n=5); Review only/not original study data (n=12); Study was performed in vitro, or no clinical outcomes measured (n=11); and, No data on hospitalization or patient-reported outcomes (n=12).

The commenter further stated that out of the remaining five publications, two were disqualified because they mentioned the outcomes of interest but did not provide information on comparator rates, with three publications ultimately identified as potentially eligible for inclusion in commenter's meta-analysis. The commenter noted that, out of those three, one showed null findings for hospital data, one showed null findings for patient reported outcomes, and the final study showed imbalance in study groups that was larger than the difference after use of the dialyzer and used inappropriate statistical analysis. The commenter stated that its analysis therefore found there were not enough robustly conducted studies for a meta-analysis to be performed, and the few that were available showed insignificant results.

The commenter opined that the potential impact of replacing the use of high-flux membranes with Theranova to increase removal of middle molecules remains inconclusive and under-studied, since to date, no strong evidence supports a survival benefit associated with increasing removal of middle molecules. The commenter is unaware of studies devoted to studying the effects of different dialyzers for

patients who are at particularly high risk for derangements in albumin synthesis. The commenter also added that, similarly, the results of studies of short duration may not adequately capture long-term trends or reflect changes in compensatory mechanisms, nutritional state over time, or worsening underlying health status. The commenter stated that given the insufficient clinical evidence to support a finding of SCI and specific concerns regarding the impact of Theranova's albumin-leaking properties, the commenter supported CMS's evaluation in the CY 2021 ESRD PPS proposed rule and strongly recommended that CMS not provide a TPNIES payment for the Theranova dialyzer.

Renal dieticians and an LDO commenters expressed their concerns about albumin loss in the dialysis patients and the risk of infection, along with it being a predictor of mortality and hospitalizations and other comorbidities. One commenter stated that a low serum albumin level complicates the fluid removal process as it causes excess fluid to shift out of the blood space, making treatment ineffective at fluid and toxin removal. Another commenter believed it was important for the applicant to generate and establish Theranova's safety data via well-controlled, randomized clinical trials of adequate duration on albumin loss in U.S. dialysis patients. The dieticians also expressed concern over the removal of other biological materials, aside from uremic toxins, such as electrolytes, insulin, sodium and potassium.

Another commenter noted that a 2019 study, which concluded that an increase of 0.25mg/dL/year in albumin decreased all-cause mortality, and more significantly a decline in albumin of 0.5 mg/dL/year or greater was associated with a 55 percent higher risk of mortality, did not provide sufficient evidence in long-term consequences to serum albumin levels to make a sound decision of approval, as it was only conducted for a short three-month span.

An organization of LDOs commented that CMS correctly applied the TPNIES SCI criteria in its analysis of the Theranova Dialyzers. The commenter noted that many of the studies presented were of a small number of patients, not conducted for an extended period of time, were not representative of the Medicare population in the U.S., and pointed out that given the Theranova dialyzers are available in Europe, they were surprised that there were no long term studies with a larger number of patients to offer insight into the relative benefit compared with other devices. The commenter also had a stated preference for seeing studies conducted in the U.S. and among the Medicare population to ensure that products are compatible with our systems of care and that devices are tested in a relevant population that is reflective of the diversity of America's Medicare beneficiaries who are reliant upon dialysis. A physician commenter agreed with the need for a randomized controlled study done in the U.S., and asserted that said study would need to ensure the diversity of participants arriving at an accurate representation of the total under care.

Several dietician commenters noted that patients in different countries had dietary habits that clearly were not reflective of the U.S., and there was no accounting for differing diet habits, which may be markedly different from the U.S. ESRD patient population. Additionally, dialysis practice differed greatly from the U.S., and thus, data gathered in small sample sizes from substantially different patient populations should not be extrapolated to U.S. Medicare patients, as the data from other countries possibly varied greatly from this specific population. One dietician commented that the sample size of the research conducted included a mere 50 individuals in 2017, making it impossible to conclude the benefit of Theranova outweighs the risks that could incur from its use.

A dialysis company commenter stated that products eligible for TPNIES should first be evaluated through research, demonstrating significant improvement in quality of life, mortality, facilitation of home therapy, or some other measurable quality metric, and that such studies should show a direct benefit or an effect on a well-established clinical parameter associated with beneficial outcome. The commenter stated that this scientifically-based standard, when applied to Theranova, made it inappropriate for the TPNIES process.

An LDO commenter identified and assessed three studies that were not included in Theranova's application or the CY 2021 ESRD PPS proposed rule. The commenter found the studies lacking in a number of critical areas, and thus not providing any additional basis for approving Theranova.

A dialysis company commenter recounted past experiences with other dialysis membrane products, namely high flux polysulphone dialysis membranes in the 1990's touted as an improvement in dialysis with enhanced clearance of beta-2-microglobulin. The commenter stated that, while their use was widely adopted and paid for by Medicare through the composite rate, when the HEMO study in 2002 finally investigated the effect of this membrane in an article published in the New England Journal of Medicine, no benefit was found. The commenter believed that this experience did not need to be duplicated with Theranova.

Response: We thank all of the commenters for their informative comments regarding the Baxter application for TPNIES for the Theranova Dialyzer. CMS evaluated the application, accompanying articles, meta-analysis and all the comments submitted. CMS evaluated all the criteria at § 413.236(b)(5) and 412.87(b)(1) to evaluate SCI for purposes of the TPNIES. In doing so, we applied the following eligibility criterion from § 412.87(b)(1)(i): ''The totality of the circumstances is considered when making a determination that a new [renal dialysis equipment or supply] represents an advance that substantially improves, relative to [renal dialysis services] previously available, the diagnosis or treatment of Medicare beneficiaries.''

CMS identified two major concerns with the information presented to CMS: (1) Studies and data presented were either low powered, did not provide statistical significance in their results, and/or did not include a control population; (2) Studies provided signals that albumin might be filtered by the product, resulting in low levels of albumin for some patients. Albumin is a critical protein that carries vitamins and other proteins through the bloodstream, as well as performing other functions. While there are some signals in the information provided by the applicant that it may be possible for some patients to have albumin levels rebound over a certain period of time, the data are considered nascent in identifying the subpopulations whose albumin levels may be able to respond appropriately to the filtering. Additionally, commenters, including a major dialysis organization noted similarities to a product that entered the market in the 1990s where the clinical data was nascent upon entry and that ultimately clinicians considered the product clinically similar to other products on the market.

Further, CMS clinicians involved in the review of the product were unable to identify subpopulations for which they believed the evidence demonstrated a substantial clinical improvement at this time. The clinicians indicated that without additional evidence they would consider this product similar to other products on the market and would need

to closely monitor albumin levels of their patients. In other words, they would consider using this product in a more observational manner rather than adopting it based on any expected outcomes. As previously noted, we did not find the submitted evidence and public comments sufficient in meeting the ''totality of the circumstances'' regulatory criterion.

Although CMS did not find the submitted evidence and public comments sufficient in meeting the ''totality of the circumstances'' criterion to qualify the Theranova Dialyzer for the TPNIES adjustment for CY 2021, we anticipate that the applicant may submit additional evidence for the Theranova Dialyzer in support of the claim of substantial clinical improvement for CY 2022. We note that the applicant is eligible to apply for the TPNIES adjustment for the Theranova Dialyzer for CY 2022 and CY 2023, and CMS would review any new information provided for the CY 2022 rulemaking cycle. A product that is determined to meet the criteria to receive the TPNIES would receive the adjustment for 2-calendar years.

b. Tablo® Cartridge for Exclusive Use With the Tablo® Hemodialysis System

(1) Outset Medical Application

For CY 2021, Outset Medical submitted an application for the TPNIES for the Tablo® Cartridge for exclusive use with the Tablo® Hemodialysis System. The applicant stated that the Tablo® Cartridge is intended to substantially improve the treatment of Medicare beneficiaries with ESRD by removing barriers to home dialysis.

The applicant noted that the Tablo® Cartridge is necessary to operate the Tablo® Hemodialysis System for use in home. The cartridge is comprised of a pre-strung blood tubing set and series of sensor-receptors mounted to a user-friendly organizer, and together these are referred to as the Cartridge. The blood tubing set comprises a blood pump tubing segment that interfaces with a peristaltic (blood) pump mounted on the inner front panel of the Tablo® console and arterial and venous lines that connect to the corresponding lines on the patient. Additional components to the cartridge include consumable supplies: Bicarbonate and acid concentrate jugs and straws, and an adapter for disinfectant use.

The applicant stated that the blood tubing set is primarily comprised of one arterial line and one venous line and is enhanced with a recirculating adaptor, a bifurcated saline line, a pressure transducer protector, a drip chamber with clot filter, and an arterial pressure pod.

According to the applicant, in addition to the blood lines, there is an integrated saline line that enables automatic priming as well as monitored delivery of saline boluses during treatment. There is also an infusion line and two infusion ports (arterial and venous) for manual delivery of medicine, anticlotting agents, and blood sampling.

In describing what the Tablo® Cartridge does, the applicant stated that it was designed with features to seamlessly integrate with sensors on the front panel of the console (for example, air sensing, arterial and venous pressure sensing) and to reduce touch points during priming and blood return (for example, recirculating adapter and bifurcated saline line) to minimize contamination. The blood pump draws blood from the patient into the blood tubing set and passes the blood through a dialyzer before returning the treated blood to the patient.

The applicant specifically stated that the Tablo® Hemodialysis System includes the Tablo® Cartridge. In its entirety, it has been specifically designed for patient-driven self-care using an iterative human factors process, with key design objectives being to facilitate learning and to minimize device training time.[146] Human factors studies performed in a laboratory setting have demonstrated that patients can accurately learn and manage the Tablo® Hemodialysis System after a brief training period.[147] [148] A recent prospective, multicenter, open-label, crossover trial comparing in-center and in-home HD using Tablo® Hemodialysis System further supported the clinical efficacy, safety, and ease of use of the system.[149]

The applicant stated that the Tablo® Hemodialysis System is the first and only all-in-one technology and includes a number of features that make it new and different from current standard of home dialysis care. These unique features include (1) A single-use Tablo® Cartridge with user-friendly pre-strung blood, saline, and infusion tubing and an integrated blood pressure monitor that interfaces with the console to enable automated features such as air removal, priming, and blood return which minimize use, user errors, save time and streamline the user experience;[150] (2) on demand water and dialysate production using a standard tap water source, eliminating the need for time-consuming advance water preparation, bagged dialysate or dialysate batching;[151] (3) a consumer-centric touchscreen interface that guides users with step-by-step instructions including non-technical language, animation, and color-coded parts, to enable easier training, faster set-up and simpler management including clear alarm explanations and resolution instructions;[152] and (4) electronic data capture and automatic wireless transmission to eliminate the need for manual record keeping by the patient, care partner, or nurse.[153]

The applicant asserted, both in the written application and at an in-person meeting with CMS, that the observational studies with the Tablo® Hemodialysis System were able to achieve CMS adequacy targeted on three times per week dialysis at an average treatment time of less than 4 hours. Tablo® has demonstrated the ability to treat to adequacy targets within the Medicare standard reimbursement of three treatments per week.

The applicant has not submitted an application for pass-through payments under the Medicare OPPS or the NTAP program under the Medicare IPPS for the Tablo® Hemodialysis System, including the Tablo® Cartridge.

This application for TPNIES is only for the Tablo® Cartridge and its components for use in the home, which the applicant stated that it intended to begin marketing in March 2020 following FDA clearance of the Tablo® Hemodialysis System for home use. On March 31, 2020, Outset Medical received FDA clearance to market the device for use in the home, and CMS received a copy of this letter.

The applicant submitted a Premarket Notification 510(k) for clearance of Tablo®. Previous 510(k) clearances for

[146] Alvarez, Luis, et al. ''Clinical Experience with a New Hemodialysis System Designed for In-Center Self-Care Hemodialysis.'' Self-Care, vol. 8, no. 3, 2017, pp. 12–18. Self-Care vol. 8, no. 3, 2017, pp.12–18.

[147] Wilcox, Stephen B., et al. ''Results of Human Factors Testing in a Novel Hemodialysis System Designed for Ease of Patient Use.'' Hemodialysis International, vol. 20, no. 4,16 May 2016, pp. 643–649.doi:10.1111/hdi.12430.

[148] Alvarez, Luis, et al. ''Tablet-Based Training for In-Center Self Dialysis—A Pilot Study.'' Journal of the American Society of Nephrology, vol. 27, no. Abstract Edition, Nov. 2016, p. 895A.

[149] Plumb, Troy et al. ''Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis.'' Hemodialysis International, Online, 2019, DOI:10.1111/hdi.12795.

[150] Outset Medical, ''Safety Reference Guide.'' DOC–0004336 Rev 04, 2019.

[151] Outset Medical, ''Tablo Preconfigured System White Paper.'' DOC–0004252 Rev 01, 2019.

[152] Alvarez, Luis, et al. ''Tablet-Based Training for In-Center Self Dialysis—A Pilot Study.'' Journal of the American Society of Nephrology, vol. 27, no. Abstract Edition, Nov. 2016, p. 895A.

[153] Outset Medical, ''Tablo Information Security Design White Paper.'' DOC–0003639 Rev 03, 2019.

the Tablo® Hemodialysis System and Tablo® Cartridge were for hospital and outpatient clinic use only. The applicant could not use or market the Tablo® Cartridge in the home setting until the Tablo® Hemodialysis System was granted marketing authorization by the FDA (note: Tablo® Hemodialysis System and cartridge was granted FDA market authorization in November 2016). While the cartridge was previously cleared through a separate 510k and was not necessary to include in the submission for marketing authorization for home use, the Tablo® Hemodialysis System cannot be operated without the Tablo® Cartridge. According to the applicant, the cartridge was included in the use instructions for the home approval.

The applicant noted that the Tablo® Cartridge is not currently available for marketing in the home setting. As explained above, the applicant intended to begin marketing in the home setting in March 2020, after the FDA cleared the Tablo® Hemodialysis System for marketing for home use. The applicant expected the first shipments of the Tablo® Cartridge for use in the home to occur March 2020, however, the first patient started training on June 1, 2020.

The applicant had an Investigational Device Exemption (IDE) to study the Tablo® Hemodialysis System's safety and efficacy for use in the home, which had been completed as of the filing of the TPNIES application. The applicant stated that the IDE would be closed once marketing authorization for the use of the Tablo® Hemodialysis System in the home was granted. The IDE study reference number was G140098. The Tablo® Cartridge was classified as a Class II device.

The applicant stated that it submitted a HCPCS application for the Tablo® Cartridge in advance of the September 1, 2020 deadline.

The applicant identified and described how the new and innovative renal dialysis equipment or supply meets the criteria for SCI over existing renal dialysis services. The applicant stated the Tablo® Cartridge is necessary to operate the Tablo® Hemodialysis System and therefore enables the system to deliver the treatments that meet CMS's SCI criteria.

The applicant stated that the Tablo® Hemodialysis System enables a treatment option for a patient population unresponsive to, or ineligible or, currently available treatments. As supporting background material, the applicant noted that home HD is a highly underutilized treatment for ESRD patients. Currently 90 percent of patients receive HD in a clinic. Fewer than 2 percent have HD treatment at home. Contributing to this low penetration rate is also a high dropout rate with the incumbent home devices of 25 percent and 35 percent at 12 and 24 months, respectively.[154] The barriers to home dialysis adoption and retention have been well studied and include: (1) Treatment burden for patients and care partner fatigue; (2) technical challenges operating HD machine; (3) space, home modifications, and supplies management; (4) patients not wanting medical equipment in the home; and (5) safety concerns.[155] [156] The applicant asserted that Tablo® is the first new home HD system in over 15 years, designed to address many of the above-mentioned barriers that currently result in patients resigning themselves to in-center care and/or stopping home modalities due to the associated burden of self-managed therapy. Among other things, the objective of this order is for 80 percent of ESRD patients starting kidney replacement therapy (KRT) with a transplant or home dialysis by 2025.[157] The applicant stated that this goal will require a multi-faceted solution, inclusive of less burdensome technology, to address the key barriers to home dialysis.

The applicant stated that the Tablo® Hemodialysis System has the potential to significantly increase home dialysis. The applicant conducted an IDE study for the primary purpose of evaluating the safety and efficacy of Tablo® Hemodialysis System use in the home setting. The applicant stated that the results from the IDE study demonstrate the following: (1) Patients will opt for home dialysis if the Tablo® Hemodialysis System is available; (2) patients have confidence in the safety and efficacy of the Tablo® Hemodialysis System; (3) the unique features of the Tablo® Cartridge as part of the Tablo® Hemodialysis System simplify set-up and use; and (4) the wireless transmission of data feature is reassuring to patients because it relieves patients of the burden of recording and fear that the patient may forget to document some aspect of treatment. The applicant claimed that the IDE study results show that these key features will facilitate growth and ongoing use of the Tablo® Hemodialysis System in the home setting.

During the course of the study, with an average treatment time of 3.4 hours, twenty-eight out of thirty patients completed all phases of the trial and no patient dropouts occurred during the in-home phase. There is only one other mobile HD machine on the market. Its IDE, based on six times per week therapy at an average treatment duration of 2.8 hours, showed a higher drop-out rate (19 percent vs Tablo's® 7 percent) and lower adherence to treatment at home (89 percent vs Tablo's® 99 percent).[158] [159]

The applicant asserted that the Tablo® Hemodialysis System significantly reduced training time for both patients and their caregivers, improving training completion and reducing patient technique failure and care partner burden. The applicant stated that the cartridge element of the Tablo® Hemodialysis System removes many of the manual steps and minimizes both set up time, and the need to make difficult connections, which requires training to avoid contamination. In human factors testing submitted to the FDA, the use of the cartridge resulted in 90 percent of the users being able to set up Tablo® in under 10 minutes.[160] The applicant stated that the Tablo® Hemodialysis System home IDE data demonstrates that on average it takes 3.5 training sessions to learn the Tablo® Hemodialysis System compared to 14.5 sessions on the device that is the current standard of care for home HD.[161] The applicant asserted that reduced training time increases likelihood of successful completion, reduces patient technique failure, and decreases caregiver burden. The applicant noted the following: (1) The graphical user interface guides users through the treatment and

[154] Sehasi, Rebecca et al. Factors Associated With Discontinuation of Home Hemodialysis, American Journal of Kidney Disease, Volume 67, Issue 4, 2016, Pages 629–637.

[155] Seshasai, R.K., et al. The home hemodialysis patient experience: A qualitative assessment of modality use and discontinuation. Hemodialysis International, 23: 139–150, 2019. doi:10.1111/hdi.12713.

[156] Chan, Christopher T. et al. Exploring Barriers and Potential Solutions in Home Dialysis: An NKF–KDOQI Conference Outcomes Report, Mar 2019, American Journal of Kidney Diseases, Volume 73, Issue 3, 363–371.

[157] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Advancing American Kidney Health, July 10, 2019.

[158] Kraus, M., et al., A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477 2007 doi:10.1111/j.1542–4758.2007.00229.x.

[159] Plumb, T.J., Alvarez, et al. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodialysis Internationa 2019l. doi:10.1111/hdi.12795.

[160] Alvarez, Luis, et al. ''Clinical Experience with a New Hemodialysis System Designed for In-Center Self-Care Hemodialysis.'' Self-Care, vol. 8, no. 3, 2017, pp. 12–18. Self-Care vol. 8, no. 3, 2017, pp.12–18

[161] Chahal, Yaadveer, Decreased Time to Independence with the Tablo Hemodialysis System: A Subset Analysis of the Tablo Home Clinical Trial, Abstract accepted for the National Kidney Foundation Spring Clinical Meeting 2020.

eliminates the need for memorization and mental math; (2) sensors and automation eliminate multiple manual steps in treatment set-up; and (3) contextual alarms instantly alert patients to any issues with their treatment and provide video and text direction on how to resolve them. This is in comparison to numerical alarm codes with the incumbent device that requires reference to the user manual or memorization with no video guidance available.

The applicant stated that the Tablo® Hemodialysis System significantly reduces set up and treatment time reducing treatment burden, improving retention at home, and reducing the need for and involvement of a care partner. The applicant noted that data from Outset Medical's Tablo® Hemodialysis System home IDE trial showed that a patient could set up the Tablo® Hemodialysis System in 9.2 minutes.[162] With the average number of treatments of 3.6 per week for an average duration of 3.4 hours,[163] a Tablo® Hemodialysis System user treating 4 times per week can expect to spend approximately 14 hours a week preparing for and conducting treatments, versus 40 hours a week on the incumbent device for patients who batch solutions.[164] [165] The applicant stated that this significant reduction in setup and treatment time is a result of software and workflow improvements incorporated in the Tablo® Hemodialysis System and its cartridge, many of which were driven by patient feedback. Reducing overall treatment burden improves modality retention at home on behalf of the patient and limits the care partner burden by reducing the need for their active involvement in treatment.

The applicant stated that the cartridge portion of the Tablo® Hemodialysis System is pre-strung and requires only two connections to operate as compared to other systems that require stringing, hanging, snapping, and tapping multiple lines. In the home IDE time set up of dialysate concentrates, the Tablo® Cartridge took less than 12 minutes on average. With an average time of 8 minutes, an uninterrupted patient can initiate therapy in as little as 20 minutes.[166] This is a significant improvement in the standard of care, which can take approximately 45 minutes.[167] The applicant asserted that the Tablo® Hemodialysis System's automatic and integrated sensors and automated degassing and priming also make the machine easier to use and quicker to set up and get to treatment.

The applicant stated that the Tablo® Hemodialysis System is the only system with a fully integrated water treatment system that allows for real-time water purification and dialysate produced on demand with no need to batch solutions or hang bags of dialysate. In addition, the applicant noted that it requires only a standard, grounded electrical outlet and Environmental Protection Agency quality tap water to operate, obviating the need to store bags of dialysate in the home, significantly reducing the number of supplies patients need to receive each month.

The applicant noted that the Tablo® Hemodialysis System reduces patient/care partner burden and technique failure. Specifically, the applicant stated that automation of processes such as prime and rinse back reduces the overall number of treatment related steps. In addition, the applicant said that the Tablo® Hemodialysis System's easy to use touchscreen interface walks users through each step of setup, treatment, and take down; the treatment information displays data that patients most wanted to see. The applicant asserts that this automation and patient-centric design reduces technique failure as evidence by results from the IDE study, which demonstrated a significant increase in treatment adherence and high rate of study completion compared to the current standard.

The applicant further stated that the Tablo® Hemodialysis System eliminates documentation burden and reduces reporting errors, and that it is the only HD system with 2-way wireless transmission delivering HIPAA compliant data to the healthcare provider without any need for additional equipment. This frees patients from the need to manually document treatment data by hand or on a separate tablet and ensures higher data accuracy.

The 28 patients who entered the home phase of the Tablo® Hemodialysis System home IDE answered weekly if they needed help with treatment over the prior seven days. The applicant stated that by the end of the study, 216 of 224 possible responses were obtained. The care partner burden rating for prior in-home patients who were previously dialyzing on the incumbent device decreased from 3.1 to 2.4 on Tablo®. Among prior in-home patients, 69 percent of patients reported needing help from a trained individual with their prior device with 46 percent of respondents stating the help needed was device related, 15 percent related to cannulation alone, and 8 percent reported other. By contrast, while on Tablo®, only 38 percent of patients reported needing help with treatment—only 22 percent needed help related to use of Tablo® while 16 percent needed help related to cannulation. The applicant asserted that this data underscores a significant decrease in patients needing assistance with treatment at home.

The applicant stated that Tablo® Hemodialysis System's unique features increase patient safety and satisfaction. The applicant noted that Tablo® Hemodialysis System's integrated, 2-way wireless connection provides clinicians with the ability to monitor patients in real time without any separate equipment necessary. The applicant asserted that the Tablo® Hemodialysis System is the only HD technology with this function, which allows for early identification and intervention by a patient's healthcare team as a key safety feature. At 34 inches tall, Tablo® Hemodialysis System user interface matches the height of a user while seated in a standard dialysis chair allowing patients to directly, and quickly engage with the integrated touch screen to view progress of the treatment, resolve alarms, and adjust certain functions to tailor the treatment to his or her needs. As an example, a patient with limited mobility can reach the interactive touch screen to adjust the flow rate if they feel cramping coming on. The IDE generated data that demonstrated how the technology enabled more rapid resolution of alarms. During the home arm of the study, patients were able to resolve alarms on the Tablo® Hemodialysis System in 5 seconds.[168] The applicant asserted that rapid resolution of alarms and enhanced communication improve safety by facilitating rapid correction of any treatment related events, limiting

[162] Outset Medical subset analysis of Home IDE Trial data on set up time for Tablo Cartridge and concentrates.

[163] Plumb, T.J., Alvarez, et al. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodialysis Internationa 2019l. doi:10.1111/hdi.12795.

[164] NxStage Medical, Transitional Dialysis Care Operational Guidance, June 2019, *https://www.nxstage.com/wpcontent/uploads/2019/06/APM2548-Rev-B-TDC-Operational-Guidance.pdf.*

[165] Kraus, M., et al., A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477 2007 doi:10.1111/j.1542–4758.2007.00229.x.

[166] Outset Medical subset analysis of Home IDE Trial data on set up time for Tablo Cartridge and concentrates.

[167] Informal interviews with NxStage patients.

[168] Wilcox, Stephen B. et al., Results of human factors testing in a novel hemodialysis system designed for ease of patient use, Hemodialysis International 2016; 20:643–649.

treatment interruptions and improving communication between the patient and provider.

Once approved for home use, the applicant stated that the Tablo® Hemodialysis System will provide a simpler, easier to use system that is likely to increase the number of people who are able to receive and remain on dialysis at home by addressing many of the well-documented, key barriers to home dialysis reported in peer-reviewed literature.

In addressing the way in which the Tablo® Hemodialysis System with its cartridge significantly improves clinical outcomes relative to the renal dialysis services previously available, the applicant focused on hospitalization and quality of life. The applicant stated that the Tablo® Hemodialysis System's 2-way wireless connection allows for real-time intervention to prevent hospitalizations. The applicant stated that during the Tablo® Hemodialysis System home IDE, the patients using the Tablo® Hemodialysis System had an all cause admission rate of 426 per 1,000 patient years. In the general dialysis population, the all cause admission rate is 1688 per 1,000 patient years and for patients who do PD, the hospitalization rate is 1460 per 1,000 patient years, highlighting that the Tablo® Hemodialysis System may significantly reduce hospitalizations and lower cost of care.[169] The applicant stated that Tablo® Hemodialysis System's integrated, 2-way wireless connection provides clinicians the ability to monitor patients in real time without any separate equipment necessary, and is the only equipment with this embedded functionality which allows for earlier identification and intervention by a patient's healthcare team and could prevent unnecessary hospitalizations for dialysis related events or missed treatments.

The applicant stated that the Tablo® Hemodialysis System can effectively deliver adequacy with 3–4 treatments per week, potentially reducing Medicare expenditures on additional dialysis treatments per week. The applicant said that among home HD patients, Medicare payment for dialysis treatments was highly variable across different regions at 3.5 to 5.7 per week.[170] In the IDE for the Tablo® Hemodialysis System, the applicant asserted that there was effectively delivered adequacy with 4 treatments per week with an average session length of 3.4 hours, resulting in an average weekly treatment duration of ~13.6 hours. An average weekly standard Kt/V of 2.8 was achieved and 94 percent of patients achieved an ultrafiltration rate within 10 percent of the prescribed value.[171] The applicant noted that a previous study of Tablo® Hemodialysis System used in the clinic showed achievement of a spKt/V of 1.2 based on 3 treatments per week including for patients over 90 kg. While the frequency of how often patients should receive dialysis is a clinical decision that should be made between the physician and the patient, the Tablo® Hemodialysis System is the only mobile HD system with clinical data showing achievement of adequacy standards and ultrafiltration endpoints for 3 and 4 treatments per week regardless of the size of the patient.[172] [173] The applicant concluded that in this way, the Tablo® Hemodialysis System has the potential to reduce Medicare expenditures on the billing of additional dialysis treatments.

The applicant stated that Tablo® Hemodialysis System's ability to deliver adequacy on fewer treatments per week may also reduce vascular access complications due to frequent cannulation.[174]

The applicant submitted several examples in four topics to demonstrate how the Tablo® Hemodialysis System improves the quality of life. The applicant noted that patients value having a high-quality daily life, ability to live well, and feeling empowered to control their outcomes over mortality.[175] The applicant asserted that the use of the Tablo® Hemodialysis System at home allows patients to have an improved quality of life and control over their outcomes.

The first topic of improved quality of life focused on sleep and reduction in fatigue. The applicant noted that kidney patients participating in an international research collaborative to identify outcome measures most important to them ranked fatigue/energy as their top priority.[176] The applicant reported that patients in the IDE who were on home HD with an incumbent device experienced a 14 percent improvement in waking up feeling rested while on the Tablo® Hemodialysis System. Additionally, 22 percent fewer patients reported having trouble staying asleep, and 15 percent fewer patients reported waking up several times during the night while on the Tablo® Hemodialysis System.[177] The applicant asserted that this data shows that the Tablo® Hemodialysis System is able to make a clinically significant improvement in the quality of life indicator most valued by dialysis patients.

The second topic of improved quality of life discussed by the applicant was improvement in the patients' experience of hypotensive events. The applicant submitted that investigators report that a drop in blood pressure was also ranked in the top 10 of symptoms rated by patients that impact their quality of life.[178] The applicant reported that a total of 12 (40.0 percent) and 8 (26.7 percent) subjects reported hypotensive events during the Tablo® Hemodialysis System treatments during the In-Center and In-Home treatment periods, respectively, compared to 27 (90.0 percent) subjects reporting hypotensive events at baseline on another HD machine. All patients who reported hypotensive events while on dialysis in the study had also reported hypotension in their baseline history.[179]

The third topic of improved quality of life was that fewer patients reported feeling cold. The applicant reported that a total of 15 (50.0 percent) subjects during the in-center treatment period and 12 (40.0 percent) subjects during the In-Home treatment period reported feeling cold while dialyzing on the

[169] United States Renal Data System. 2019 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2019, Executive Summary Reference Table G2.

[170] Wilk, Adam S. et al., Persistent Variation in Medicare Payment Authorization for Home Hemodialysis Treatments Health services research vol. 53,2 (2018): 649–670.

[171] Plumb, T.J., Alvarez, et al. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodialysis International, 2019. doi:10.1111/hdi.12795.

[172] Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice Weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[173] Alvarez, Luis and Chertow, Glenn, Real World In-Center Urea Clearance Experience with a Novel Hemodialysis System, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[174] Agency for Healthcare Quality and Research, End Stage Renal Disease in the Medicare Population: Frequency and Duration of Hemodialysis and Quality of Life Assessment, Draft Technology Assessment, Agency for Healthcare Quality and Research November 22, 2019.

[175] Urquhart-Secord, Rachel et al Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study American Journal of Kidney Diseases, Sept. 2016, Volume 68, Issue 3, 444–454.

[176] Ibid.

[177] Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodialysis International. doi:10.1111/hdi.12795.

[178] Urquhart-Secord, Rachel et al. Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study American Journal of Kidney Diseases, Sept. 2016, Volume 68, Issue 3, 444–454.

[179] Outset Medical Data from Home IDE Trial, pg 33 of clinical report submitted to the Food and Drug Administration, data table 43, 2019.

Tablo® Hemodialysis System compared to 28 (93.3 percent) subjects who reported feeling cold at baseline while dialyzing on another dialysis machine. The applicant asserted that the Tablo® Hemodialysis System's design results in tight control of dialysate temperature and allows patients to easily and accurately adjust temperature through the graphical user interface.[180]

The fourth topic of improved quality of life was patient preference for the Tablo® Hemodialysis System. The applicant stated that the Kidney Health Initiative (KHI), a public private partnership between the FDA and the American Society of Nephrology, Renal Replacement Therapy (RRT) Roadmap prioritizes patient-centered innovation, which includes dialysis equipment that is more portable, removes barriers to home dialysis and improves patients' ease of use to increase opportunities for self-care. The RRT, which was developed in conjunction with patients, also prioritizes patient centered outcomes and technology that reduces disruption in social and family life.[181] The applicant reported that among prior home HD users in the IDE trial, 85 percent reported they preferred the Tablo® Hemodialysis System to their current equipment.[182] Patients also rated Tablo® as easier to set-up, treat, and take down. Ease of use ratings comparing the patient's prior device to Tablo® were as follows: Set up—3.5 to 4.5, Treatment—3.3 to 4.6, Take Down—3.8 to 4.6.[183]

In summary, the applicant submitted that the Tablo® Hemodialysis System has the potential to significantly expand the number of patients who are able to receive home HD and persist on the therapy. The applicant stated that it is an innovative HD system that removes most of the device-related key barriers, reduces dialysis-related symptoms, is mobile and easy to use, and therefore minimizes dialysis-related disruptions in patients' lives.

(2) CMS Analysis

(a) Summary of Current Technology

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42180), patients with ESRD who are not able to receive a kidney transplant must undergo maintenance dialysis therapy. Patients can receive dialysis 3–4 days a week at an in-center HD facility, or they can administer dialysis themselves at home. Due to the reliance on outpatient dialysis units, numbers of patients utilizing home dialysis in the U.S. have remained low. In 2017, only 10.8 percent of US dialysis patients received home-based therapies.[184] Patients and caregivers cite concerns with self-cannulation, fears of needle disconnect and complications.[185] Home dialysis use is lower than many other rich countries.[186]

Most patients administering dialysis at home use PD. However, home HD has more recently re-emerged as an alternative way for patients to dialyze at home. Home HD may offer many of the advantages observed with PD, such as increased flexibility and quality-of-life benefits. However, adoption of home HD has been limited, with approximately only 1 percent of ESRD patients utilizing this modality.[187]

Observational studies do not indicate significant differences in survival when comparing home dialysis to in-center dialysis.[188] Yet, there are some potential benefits to home-based dialysis. Prior analyses have noted that home-based dialysis affords greater patient flexibility, improved quality of life,[189] increased likelihood of employment,[190] and improved cost.[191] However, regarding cost comparisons, it is important to note that many cost analyses of home-based dialysis include estimates from PD. The machines for HD are costly and there may be higher rates of infection from self-cannulation, which could offset any savings. Since such a small percentage of patients receive home-based HD, it is challenging to know actual cost without pooling it with PD estimates. Regardless, due to an Executive order issued in 2019, economic incentives for home dialysis (both peritoneal and home HD) were increased with the goal of expanding its use.[192]

(b) Description of New Technology

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42181), the first personal HD system on the market was called the Aksys personal HD (Aksys Ph.D.) system. It created its own ultrapure dialysate and was FDA cleared in 2002. It later underwent recall in 2006 due to marketing inconsistencies with system design.[193] Eventually, the manufacturer shut down operations after difficulties in securing financing.[194] In addition to these issues, it was a large machine that required significant patient utility resources and specialized maintenance.[195] Around this time, development of the Allient dialysis system began, which utilizes a sorbent column to regenerate dialysate from tap water.[196] It is still in development for potential home based therapy.

Several home dialysis machines are currently available. Recently, the NxStage® System One dialysis machine was FDA approved for 510(k) premarket status in August 2017.[197] It has a smaller profile than the Aksys machine

[180] Ibid.

[181] Kidney Health Initiative, Technology Roadmap for Innovative Approaches to Renal Replacement Therapy, prepared by the Nexight Group, October 2018, *https://www.asnonline.org/g/blast/files/KHI_RRT_Roadmap1.0_FINAL_102318_web.pdf.*

[182] Chahal, Yaadveer, Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial, Abstract Accepted by the National Kidney Foundation Spring Clinical Meeting 2020.

[183] Outset Medical Data from Home IDE Trial, pg 33 of clinical report submitted to the Food and Drug Administration, data table 43, 2019.

[184] United States Renal Data System (USRDS). 2019 Annual Data Report: Reference Tables. *https://www.usrds.org/reference.aspx.* Last Access Date Feb 20, 2020.

[185] Young BA, Chan C, Blagg C, Lockridge R, Golper T, Finkelstein F, Shaffer R, Mehrotra R; ASN Dialysis Advisory Group. How to overcome barriers and establish a successful home HD program. Clin J Am Soc Nephrol. 2012 Dec;7(12):2023–32. doi: 10.2215/CJN.07080712. Epub 2012 Oct 4.

[186] Wilkie M. Home dialysis—an international perspective. NDT Plus. 2011 Dec;4(Suppl 3):iii4–iii6.

[187] Mailloux LU, Blagg CR. Berns JS (ed.) Home Hemodialysis. Uptodate. Nov 18, 2016.

[188] Chiu YW, Jiwakanon S, Lukowsky L, Duong U, Kalantar-Zadeh K, Mehrotra R. An update on the comparisons of mortality outcomes of hemodialysis and peritoneal dialysis patients. Semin Nephrol. 2011;31:152–158.

[189] Rubin HR, Fink NE, Plantinga LC, Sadler JH, Kliger AS, Powe NR. Patient ratings of dialysis care with peritoneal dialysis vs hemodialysis. JAMA. 2004;291:697–703.

[190] Muehrer RJ, Schatell D, Witten B, Gangnon R, Becker BN, Hofmann RM. Factors affecting employment at initiation of dialysis. Clin J Am Soc Nephrol. 2011 Mar;6(3):489–96.

[191] Berger A, Edelsberg J, Inglese GW, Bhattacharyya SK, Oster G. Cost comparison of peritoneal dialysis versus hemodialysis in end-stage renal disease. American Journal of Managed Care. 2009;15:509–518.

[192] The White House. Executive order on Advancing American Kidney Health. July 10, 2019. *https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/* Last Access Date Feb 18, 2020.

[193] Food and Drug Administration. Class 2 Device Recall Aksys Ph.D. Personal Hemodialysis System. Medical Devices Database. June 2006. *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=46686.*

[194] Modern Healthcare. Dialyais machine firm Aksys shuts down. Feb 21, 2007. *https://www.modernhealthcare.com/article/20070221/NEWS/70221010/dialysis-machine-firm-aksys-shuts-down.* Last Access Date Feb 18, 2020.

[195] Mailloux LU, Blagg CR. Berns JS (ed.) Home Hemodialysis. Uptodate. Nov 18, 2016.

[196] Ash SR. The Allient dialysis system. Semin Dial. 2004 Mar–Apr;17(2):164–6.

[197] Food and Drug Administration. Traditional Section 510(k) Premarket Notification Letter, Number K171331. August 24, 2017. *https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171331.pdf.*

but requires 4 to 6 large bags of ultrapure dialysate and comes with home storage requirements. The NxStage® PureFlow SL was subsequently developed for use with the NxStage® System One. It allows patients to prepare dialysate from tap water with a reduced need to store dialysate bags. The NxStage® system advertises an easier experience learning how to administer home dialysis. Within this arena, the Tablo® Hemodialysis System has recently emerged and been approved for use in hospitals and outpatient settings. The Tablo® Hemodialysis System is most comparable to NxStage System One combined with NxStage® PureFlow, in that it may be easier to use than conventional home dialysis machines and can be used from a tap water source. The applicant is currently pursuing approval for use of cartridges for the Tablo® Hemodialysis System in the home setting. While this application centers on reimbursement of the Tablo® Cartridge, this cartridge is only compatible with the Tablo® Hemodialysis System. The cartridge is made up of a rigid ''Organizer'' which mounts the necessary tubing to allow for greater ease in set-up. This self-contained and single-use cartridge houses both the arterial and venous lines, an adaptor to connect the lines, a saline line, and an infusion line. There is also a pressure transducer protector, venous drip chamber with clot filter, and an arterial pressure pod. The applicant noted that the cartridge simplifies connection to the Tablo® Hemodialysis System and reduces set-up time. It would seem that this cartridge would be most useful in the home-setting, since hospital and clinic settings would normally have trained personnel to assist with set-up. Although separate from the Tablo® Cartridge, the Tablo® Hemodialysis System also performs real-time water purification on demand dialysate production.

A significant challenge to increasing the use of home dialysis includes burn out (or technique failure) and return to in-center HD. According to one recent observational study, approximately 25 percent of patients who initiate home HD return to in-center HD within the first year.[198] A good measure of a home-based system's success would be in its ability to allow patients to remain on the therapy long-term. Failure to maintain home HD, and low use of home HD, may be a result of anxiety and unease that many patients have about performing the treatment themselves (or with the help of care takers).[199] [200] [201] This includes fear of self-cannulation in order to access the blood for dialysis and a lack of self-efficacy in performing the therapy. By simplifying the process of setting up dialysis tubing, offered by the Tablo® Hemodialysis System cartridge, some patients may be able to successfully perform home HD.

(c) Approvals

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42181), the applicant has not previously submitted applications for pass-through or add-on payments. The applicant has received 510(k) marketing clearance for the machine to be used in hospital and outpatient clinic use only. As such, the applicant is pursuing FDA marketing authorization for use in the home setting for February 2020. The Tablo® Hemodialysis System cartridge received FDA marketing approval in December, 2019 and the Tablo® Hemodialysis System received FDA marketing authorization for home setting in March 2020. The applicant noted that upon approval, the company plans to ship that same month. The technology had an investigational device exemption for use in the home and which closed after granting of marketing authorization. It is classified as a Class II device.

(d) Assessment of Substantial Similarity to Currently Available Technology

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42182), the NxStage® One is the only home-based HD system that is FDA has approved at this time. The Tablo® Hemodialysis System differs from the NxStage® in that dialysate is produced on demand whereas the NxStage® requires that patients batch dialysate or use pre-filled concentrate with the PureFlow. The Tablo® Hemodialysis System also includes a cartridge (which is the portion being evaluated for TPNIES) designed to facilitate the connection of tubing in the appropriate configuration. This product treats similar patients, notably patients with ESRD requiring HD.

(e) Assessment of SCI (See §§ 413.236(b)(5) and 412.87(b)(1))

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42182), the Tablo® Hemodialysis System is a treatment modality, not a diagnostic tool. With regard to the question as to whether this new renal dialysis equipment offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we note that patients who are eligible for this treatment would currently be eligible for in-center HD, home HD with currently available treatments, and possibly PD.

(f) Clinical Evidence for Claims of SCI

As stated in the CY 2021 ESRD PPS proposed rule (85 FR 42182 through 42183), the applicant included an annotated bibliography in its application. Many of the articles describe the features of the HD system: Straightforward and relatively efficient set-up and training, presence of safety features, water purification system, and wireless communication. In terms of clinical outcomes and improvements, the referenced authors have presented or published data on safety, clearance and treatment times, hypotensive events and cold symptoms, and patient preference. As these are arguably more important considerations, we are focusing on the evidence with those claims of clinical improvement or patient reported outcomes.

Below is a list of references for SCI based on evidence published from several sources. We summarized the studies grouped by listings with the most rigorous review to those with the least rigorous review, specifically, Trials Published in Peer-Reviewed Journals, then Posters and Abstracts, and ending with Unpublished Data.

Trials Published in Peer-Reviewed Journals

- Plumb TJ, et al.[202] describes the IDE study, which was a prospective, multicenter, open-label crossover trial evaluating in-center versus in-home use of the Tablo® Hemodialysis System. Thirty patients underwent a run-in period, 8 weeks of in-center therapy (4 treatments a week), then a 4-week transition period, and finally an 8-week in-home treatment (4 times a week).

[198] Seshasai RK, Mitra N, Chaknos CM, Li J, Wirtalla C, Negoianu D, Glickman JD, Dember LM. Factors Associated With Discontinuation of Home Hemodialysis. Am J Kidney Dis. 2016 Apr;67(4):629–37.

[199] Cafazzo JA, Leonard K, Easty AC, Rossos PG, Chan CT. Patient-perceived barriers to the adoption of Nocturnal Home Hemodialysis. Clin J Am Soc Nephrol. 2009;4:784–789.

[200] Suri RS, Larive B, Garg AX, et al. Burden on caregivers as perceived by hemodialysis patients in the frequent Hemodialysis network (FHN) trials. Nephrol Dial Transplant. 2011;26:2316–2322.

[201] Zhang AH, Bargman JM, Lok CE, et al. Dialysis modality choices among chronic kidney disease patients: Identifying the gaps to support patients on home-based therapies. Int Urol Nephrol. 2010;42:759–764.

[202] Plumb TJ, Alvarez L, Ross DL, Lee JJ, Mulhern JG, Bell JL, Abra G, Prichard SS, Chertow GM, Aragon MA. Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodial Int. 2020 Jan;24(1):22–28. doi: 10.1111/hdi.12795. Epub 2019 Nov 7.

Authors evaluated efficacy in effective removal of uremic toxins, as measured by a weekly standard Kt/Vurea ≥2.1 and a secondary endpoint of delivered ultrafiltration within 10 percent of prescribed. Twenty-eight out of 30 patients completed the study. One patient died from cardiac arrest and the authors felt it was unrelated to the treatments. Another patient withdrew prior to starting in-home HD. There were primary outcomes, secondary outcomes, adverse event rates, alarms per treatment, and alarm response times between the two groups. Patients demonstrated high adherence rates of 96 percent, and 99 percent for the in-center and in-home groups, respectively. There is bias from the open-label study and this is a small study conducted over a short period of 12 weeks total, 4 weeks of in-home dialysis. Long-term and larger studies would be helpful to capture any safety signals. Some authors serve as Chief Medical Officer or consultants for Outset Medical.

• Kraus M, et al.[203] is a study involving the comparator technology known as NxStage® System, which is a portable HD unit. This was a prospective, open-label, crossover study comparing in-center HD versus home HD in 32 patients over 18 weeks total. The primary endpoint was delivery of 90 percent prescribed fluid volume, which was achieved in similar fashion and >90 percent in both groups. There were statistically significant differences in adverse events, which favored the home HD group. The applicant included this study to demonstrate similar evidence as well as compare time spent in performing the home sessions. Treatment durations were slightly shorter than what was noted in the IDE study above (mean 2.8 hours for NxStage® versus mean 3.4 hours with Tablo® Hemodialysis System). This study was supported by NxStage® Medical Inc.

Posters/Abstracts

• Alvarez, Luis et al.[204] is a retrospective study, 29 patients underwent HD with the Tablo® Hemodialysis System at a lower flow rate than what is used in conventional in-center HD. Average treatment times were slightly higher in the Tablo® Hemodialysis System group compared to those using non-Tablo® systems. After patient weight stratification at 90 kg, authors felt that both groups achieved similar weight changes (extrapolated from pre and post weights), as well as Kt/Vurea change. This research was funded by Outset Medical, Inc.

• Alvarez, Luis et al.[205] utilized lower flow rates of 300 ml/min, and evaluated patients as they transitioned to in-center but self-directed HD with Tablo® Hemodialysis System. Patients underwent 3 times a week treatment and data was collected over a 3-month period. Based on urea samples and calculated Kt/Vurea, authors concluded that this treatment resulted in adequate clearance.

• Chahal, Yaadveer[206] is a study that focused on the patient experience through surveys and compared the patient's responses to prior in-home and in-center experiences. As part of the IDE study, 13 participants provided survey responses to compare their experience with the Tablo® Hemodialysis System to their prior experience with in-home dialysis. Of those 13 participants, 85.6 percent found this system easier to use. While this is promising, the true test of superiority in this realm would be rates of discontinuation at 1 year. Issues of self-cannulation and the burden of this responsibility still remain with this system. The primary study was undertaken by Outset Medical.

Unpublished Data

• Outset Medical Data[207] is a limited section, in which the applicant submitted cold and hypotensive events while on in-center or in-home HD. From just raw numbers, there were lower percentages of either sign/symptom within the home dialysis group compared to in-center.

(g) CMS Comments

As discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42183), only the Tablo® Cartridge portion of the Tablo® Hemodialysis System was evaluated in this application, but it is important to note that it can only be used with the Tablo® Hemodialysis System. Although there are changes to the Tablo® Hemodialysis System for home use, the cartridge portion remains unchanged from its original FDA approval. Therefore, the cartridge itself is not new. Also, it is unclear as to whether the Tablo® Hemodialysis System can be used in-center without the cartridge. As such, much of the evidence presented in this application is really about the system itself, such as ease of training, its various features, and less about the incremental benefit of using the cartridge. Additionally, the system itself may have its own risks and benefits which are not within the scope of this application, and peripherally and incompletely addressed with the provided materials. For example, a study should be conducted determining the number of patients who were back in the hospital for a dialysis-related condition.

In the CY 2021 ESRD PPS proposed rule (85 FR 42183), we stated that to evaluate the cartridge, it would be helpful to have studies on whether there are any issues with the components of the cartridge (that is, any dialyzer reactions to tubing, any issues affecting clearance). Since the primary intent of the cartridge is to facilitate patient set-up at home, the most useful evidence would be in the form of larger studies of patient-reported outcomes, quality of life, analyses of patient/caregiver burnout, and sustained adherence (beyond 1 year) to the use of this home-based modality. If the applicant is claiming to improve the patients' quality of life, then it needs to be proven for patient-specific outcomes and with a risk-benefit analysis to the patient. In some of the references cited, the patient factors affecting home HD are self-cannulation, burdens to caregivers, and concerns for complications, yet the cartridge has not demonstrated improvements in addressing these issues.

We stated that the cartridge is a promising concept to encourage home HD but again, the evaluation of this technology is complicated by the need to also peripherally assess the system. There does not appear to be a need for this cartridge in the hospital or clinic setting as trained personnel should be able to assist with set-up. Within the larger policy context of FDA approval and the fact that TPNIES does not currently cover capital-related assets, we believe there are some irregularities and misalignments in the current application, and we are concerned that the stand-alone cartridge cannot be evaluated for meeting the criteria for SCI.

[203] Kraus M, Burkart J, Hegeman R, Solomon R, Coplon N, Moran J, A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477, (2007).

[204] Alvarez L, Spry L. Mulhern J, Prichard S, Shallall C, Chertow G, Aragon, M, Urea Clearance Results in Patients Dialyzed Thrice Weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[205] Alvarez, Luis and Chertow, Glenn, Real World In-Center Urea Clearance Experience with a Novel Hemodialysis System, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[206] Chahal, Yaadveer. Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial, Abstract Accepted by the National Kidney Foundation Spring Clinical Meeting 2020.

[207] Outset Medical Data from Home IDE Trial, page 33 of clinical report submitted to the FDA, data Table 43, 2019.

The Outset Medical application was submitted only for the Tablo® Cartridge, which can only be used with the Tablo® Hemodialysis System. As background, the Tablo® Hemodialysis System originally received FDA marketing authorization for hospital and outpatient use on November 15, 2016. Without any additional studies being required, an FDA marketing authorization was issued for just the cartridge on December 19, 2019. An application was submitted by Outset Medical to the FDA for home use of only the Tablo® Hemodialysis System, not the cartridge. FDA marketing authorization was issued for the Tablo® Hemodialysis System on March 31, 2020. Therefore, with regard to the application for TPNIES for the Tablo® Cartridge, it does not meet the newness requirement at § 413.236(b)(2), which specifies that the item is granted FDA marketing authorization on or after January 1, 2020.

We invited public comment as to whether the stand-alone cartridge of the Tablo® Hemodialysis System meets the SCI criteria for the TPNIES.

The collective comments and our response to them are set forth below.

Comment: The applicant suggested that because a HD system received approval for home use, the system and cartridge can be marketed in the same home setting. Additionally, the applicant stated, because the system and cartridge must operate together, the SCI should be linked. The applicant disagrees with the idea of only the cartridge being relevant.

Another commenter stated that according to the TPNIES policy CMS finalized for payment in CY 2021, the equipment or supply being considered for an add-on payment must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. The commenter stated that the evidence submitted by the applicant describes the features of the Tablo® Hemodialysis System and only the system. They noted that the applicant does not offer support for its assertion that the Tablo® Cartridge substantially improves the diagnosis or treatment of Medicare beneficiaries relative to dialysis services previously available. The commenter stated that because the application offers no clinical evidence on the cartridge itself, the subject of the application, it does not meet the eligibility requirements and CMS should not approve the TPNIES for this product for CY 2021.

A commenter noted that the studies that were performed were only on the Tablo® Hemodialysis System and not on the cartridge, which is the subject of the TPNIES application.

Response: CMS is supportive of new and innovative supplies and equipment for renal dialysis services. However, the Tablo® Cartridge does not meet the newness eligibility criteria of § 413.236(b)(2). Since the publication of the CY 2021 ESRD PPS proposed rule, we have learned that the Tablo® Cartridge and Tablo® Hemodialysis System have two different dates for FDA marketing authorizations. The FDA marketing authorization was issued for just the cartridge on December 19, 2019, which pre-dates the eligibility date for the TPNIES of January 1, 2020. Therefore, the cartridge does not meet the newness criterion.

In addition, CMS agrees with the commenters that the application for the cartridge only included studies applicable to the Tablo® Hemodialysis System as a whole and the cartridge by itself does not show evidence of SCI. Therefore, we are not approving the Tablo® Cartridge for as eligible for the TPNIES for CY 2021.

III. CY 2021 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies in order to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2021 Payment for Renal Dialysis Services Furnished to Individuals With AKI

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program'' (85 FR 42132 through 42208), hereinafter referred to as the ''CY 2021 ESRD PPS proposed rule,'' was published in the **Federal Register** on July 13, 2020, with a comment period that ended on September 4, 2020. In that proposed rule, we proposed to update the AKI dialysis payment rate. We received 4 public comments on our proposal, including comments from ESRD facilities, national renal groups, transplant organizations, and nurses.

We also received several comments related to issues that we either did not discuss in the proposed rule or that we discussed for the purpose of background or context, but for which we did not propose changes. These include, for example, AKI dialysis in the home, modifications to claims and cost reports to monitor AKI dialysis, and Conditions of Coverage specific to AKI dialysis. While we are not addressing those comments in this final rule because they are either out of scope of the proposed rule or concern topics for which we did not propose changes, we thank the commenters for their input and will consider the recommendations in future rulemaking.

In this final rule, we provide a summary of the proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing for CY 2021 payment for renal dialysis services furnished to individuals with AKI.

C. Annual Payment Rate Update for CY 2021

1. CY 2021 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket payment update, geographic wage adjustments and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.4.d of the CY 2021 ESRD PPS proposed rule and section II.B.4.d of this final rule, the CY 2021 ESRD PPS base rate is $253.13, which reflects the application of the CY 2021 wage index budget-neutrality adjustment factor of .999485, a final addition to the ESRD PPS base rate to include calcimimetics, and the CY 2021 ESRDB market basket increase of 1.9 percent reduced by the multifactor productivity adjustment of 0.3 percentage point, that is, 1.6 percent. Accordingly, we are finalizing a CY 2021 per treatment payment rate of $253.13 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index as discussed below.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket increase that is reduced by the multifactor productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.4.b of this final rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated previously, we are finalizing a CY 2021 AKI dialysis payment rate of $253.13, adjusted by the ESRD facility's wage index.

The comments and our responses to the comments on our AKI dialysis payment proposal are set forth below.

Comment: Commenters were supportive of the updates to the AKI dialysis payment rate for CY 2021.

Response: We appreciate the comments in support of the update.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, the AKI payment rate is based on the finalized ESRD PPS base rate. Specifically, the final CY 2021 ESRD PPS base rate is $253.13. Accordingly, we are finalizing a CY 2021 payment rate of $253.13 for renal dialysis services furnished by ESRD facilities to individuals with AKI.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the following final rules:

- CY 2011 ESRD PPS final rule (75 FR 49030),
- CY 2012 ESRD PPS final rule (76 FR 628),
- CY 2012 ESRD PPS final rule (76 FR 70228),
- CY 2013 ESRD PPS final rule (77 FR 67450),
- CY 2014 ESRD PPS final rule (78 FR 72156),
- CY 2015 ESRD PPS final rule (79 FR 66120),
- CY 2016 ESRD PPS final rule (80 FR 68968),
- CY 2017 ESRD PPS final rule (81 FR 77834),
- CY 2018 ESRD PPS final rule (82 FR 50738),
- CY 2019 ESRD PPS final rule (83 FR 56922), and
- CY 2020 ESRD PPS final rule (84 FR 60713).

We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Summary of the Proposed Provisions, Public Comments, Responses to Comments, and Finalized Policies for the ESRD QIP

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program'' (85 FR 42132 through 42208), referred to as the ''CY 2021 ESRD PPS proposed rule,'' was published in the **Federal Register** on July 13, 2020, with a comment period that ended on September 4, 2020. In that proposed rule, we proposed updates to the ESRD QIP for PY 2023, and included policies continuing for PY 2024. We received a diverse range of public comments on our proposals, including comments from large dialysis organizations, renal dialysis facilities, national renal groups, nephrologists, patient organizations, patients and care partners, health care systems, nurses, renal dietitians, and other stakeholders.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ESRD QIP.

C. Updates to Requirements Beginning With the PY 2023 ESRD QIP

1. PY 2023 ESRD QIP Measure Set

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues (77 FR 67475). Accordingly, the PY 2023 ESRD QIP measure set will include the same 14 measures as the PY 2022 ESRD QIP measure set. These measures are described in Table 6 of this final rule. For the most recent information on each measure's technical specifications for PY 2023, we refer readers to the CMS ESRD Measures Manual for the 2021 Performance Period.[208]

[208] *https://www.cms.gov/files/document/esrd-measures-manual-v60.pdf.*

TABLE 6—PY 2023 ESRD QIP MEASURE SET

National quality forum (NQF) #	Measure title and description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure. Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
2496	Standardized Readmission Ratio (SRR), a clinical measure. Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on NQF #2979	Standardized Transfusion Ratio (STrR), a reporting measure. Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure. A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure. Measures the use of an arteriovenous (AV) fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure. Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a clinical measure. Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure. Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate (UFR), a reporting measure.* Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure. Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure. Percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure. Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.

Note: *After consideration of the comments, we are finalizing our proposal to update the scoring methodology used to calculate the Ultrafiltration Rate reporting measure so that facilities are scored based on the number of eligible patient-months, instead of facility-months, and refer readers to section IV.C.3 of this final rule for a discussion of this new scoring methodology.

We did not propose to adopt any new measures for the PY 2023 ESRD QIP measure set.

2. Performance Standards for the PY 2023 ESRD QIP

Section 1881(h)(4)(A) of the Social Security Act (the Act) requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We recently codified definitions for the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

In the CY 2020 ESRD PPS final rule (84 FR 60728), we set the performance period for the PY 2023 ESRD QIP as CY 2021 and the baseline period as CY 2019. In the CY 2021 ESRD PPS proposed rule (85 FR 42185 through 42186), we estimated the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2023 clinical measures in Table 7 using data from 2018.

TABLE 7—ESTIMATED PERFORMANCE STANDARDS FOR THE PY 2023 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold (15th percentile of national performance) *	Median (50th percentile of national performance) *	Benchmark (90th percentile of national performance) *
Vascular access type (VAT):			
Standardized Fistula Rate	53.72%	64.96%	77.31%
Catheter Rate	17.70%	10.50%	4.32%
Kt/V Comprehensive	93.56%	97.13%	99.24%
Hypercalcemia	1.77%	0.58% (0.59%)	0.00%
Standardized Readmission Ratio	1.268 (1.269)	0.998	0.629 (0.641)
Standardized Transfusion Ratio [209]	1.675	0.830	0.173
NHSN BSI	1.365	0.604	0
Standardized Hospitalization Ratio	1.248	0.967 (0.976)	0.670 (0.677)
PPPW	8.12%	16.73%	33.90%
ICH CAHPS: Nephrologists' Communication and Caring	58.12%	67.89%	78.52% (78.35%)
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16 (53.87%)	62.47%	72.11%
ICH CAHPS: Providing Information to Patients	74.09%	80.48%	87.14%
ICH CAHPS: Overall Rating of Nephrologists	49.33% (47.92%)	62.22% (60.59%)	76.57% (75.16%)
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12% (48.59%)	63.04% (62.99%)	77.49%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98% (53.46%)	68.59%	83.03%

Note: We stated in the CY 2021 ESRD QIP proposed rule that if the PY 2023 final numerical value is worse than the PY 2022 finalized value, we will substitute the PY 2023 final numerical value for the PY 2022 finalized value. We also provided the PY 2023 finalized value as a reference in parentheses for clinical measures whose PY 2023 estimated value is worse than the PY 2022 finalized value.

Data sources: VAT measures: 2018 CROWNWeb; SRR, SHR: 2018 Medicare claims; Kt/V: 2018 CROWNWeb; Hypercalcemia: 2018 CROWNWeb; NHSN: 2018 CDC; ICH CAHPS: CMS 2018; PPPW: 2018 CROWNWeb and 2018 OPTN.

We are now updating the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2023 clinical measures as shown in Table 8, using the most recently available data, which includes CY 2019 data.

TABLE 8—FINALIZED PERFORMANCE STANDARDS FOR THE PY 2023 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold (15th percentile of national performance)	Median (50th percentile of national performance)	Benchmark (90th percentile of national performance)
Vascular access type (VAT):			
Standardized Fistula Rate	53.29%	64.36%	76.77%
Catheter Rate	18.35%	11.04%	4.69%
Kt/V Comprehensive	94.33%	97.61%	99.42%
Hypercalcemia	1.54%	0.49%	*0.00%
Standardized Readmission Ratio	*1.268	*0.998	*0.629
NHSN BSI	1.193	0.516	*0
Standardized Hospitalization Ratio	*1.248	*0.967	*0.670
PPPW	*8.12%	*16.73%	*33.90%
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.64%	63.08%	72.66%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	*49.33%	*62.22%	*76.57%
ICH CAHPS: Overall Rating of Dialysis Center Staff	50.02%	63.37%	78.30%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.51%	69.04%	83.72%

Note: Values marked with an asterisk (*) are also the final performance standards for those measures for PY 2022. In accordance with our longstanding policy, we are finalizing those numerical values for those measures for PY 2023 because they are higher standards than the PY 2023 numerical values for those measures.

Data sources: VAT measures: 2019 CROWNWeb; SRR, SHR: 2019 Medicare claims; Kt/V: 2019 CROWNWeb; Hypercalcemia: 2019 CROWNWeb; NHSN: 2019 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 CROWNWeb and 2019 OPTN.

In addition, we have summarized in Table 9 existing requirements for successful reporting on reporting measures in the PY 2023 ESRD QIP.

[209] The STrR measure was included in our table in the CY 2021 ESRD PPS proposed rule (84 FR 60728), however these thresholds do not apply because this is a reporting measure, as is more fully addressed in response to comment below.

TABLE 9—REQUIREMENTS FOR SUCCESSFUL REPORTING ON THE PY 2023 ESRD QIP REPORTING MEASURES

Measure	Reporting frequency	Data elements
Ultrafiltration	4 data elements are reported for every HD Kt/V session during the week of the monthly Kt/V draw, and Kt/V date is reported monthly.	• In-Center Hemodialysis (ICHD) Kt/V Date. • Post-Dialysis Weight. • Pre-Dialysis Weight. • Delivered Minutes of BUN Hemodialysis. • Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting Month.
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: ○ Physician, ○ nurse, ○ ARNP, ○ PA, ○ pharmacist, or ○ pharmacy technician personnel. • Name of eligible professional.
Clinical Depression Screening and Follow-Up.	1 of 6 conditions reported annually	• Screening for clinical depression is documented as being positive and a follow-up plan is documented. • Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. • Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. • Screening for clinical depression documented as negative and no follow-up plan required. • Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. • Clinical depression screening not documented, and no reason is given.
NHSN Dialysis Event	Monthly data reported quarterly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
STrR		At least 10 patient-years at risk during the performance period.

We received a few comments on the PY 2023 ESRD QIP measure set.

Comment: One commenter expressed general agreement with CMS's policy to maintain current structural ESRD QIP policies. The commenter also expressed support for the proposed updates to the performance standards applicable to PY 2023.

Response: We thank the commenter for its support.

Comment: One commenter requested clarification that the Standardized Transfusion Ratio (STrR) measure will be a reporting measure. The commenter noted that the measure was listed in the CY 2021 ESRD PPS proposed rule as a reporting measure in the PY 2023 measure set but was included in the Estimated Performance Standards for PY 2023 Clinical Measures table.

Response: We appreciate the commenter bringing this issue to our attention. We inadvertently included clinical performance standards for the STrR measure in Table 7 of the CY 2021 ESRD PPS proposed rule. In the CY 2020 ESRD PPS final rule (84 FR 60720 through 60723), we finalized that beginning with the PY 2022 ESRD QIP, we would convert the STrR clinical measure to a reporting measure and would score the measure based on the performance standards listed in Table 6 of that final rule, which provided that the applicable reporting performance standard for the STrR reporting measure is calculated annually and requires a facility to have at least 10 eligible patient-years at risk over the course of the performance period (84 FR 60718). The reporting requirements for the STrR measure are also included in Table 9 of this final rule.

3. Update to the Scoring Methodology for the Ultrafiltration Rate Reporting Measure

In the CY 2017 ESRD PPS final rule, we adopted the Ultrafiltration Rate reporting measure under the authority of section 1881(h)(2)(B)(ii) of the Act (81 FR 77912). The measure assesses the number of months for which a facility reports all data elements required to calculate ultrafiltration rates (UFR) for each qualifying patient. It is based upon the NQF-endorsed Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hr) (NQF #2701), which assesses the percentage of patient-months for patients with a UFR greater than or equal to 13 ml/kg/hr.

In the CY 2017 ESRD PPS final rule (81 FR 77917), we also finalized a policy to score the Ultrafiltration Rate reporting measure using the following equation, beginning in PY 2020 (81 FR 77917):

$$\left(\frac{\text{\# months successfully reporting data}}{\text{\# eligible months}} \times 12\right) - 2$$

In the CY 2021 ESRD PPS proposed rule (85 FR 42186 through 42187), we proposed to replace the current Ultrafiltration Rate reporting measure scoring equation with the following equation, beginning with PY 2023:

$$\left(\frac{\text{number of patient-months successfully reporting data}}{\text{number of eligible patient-months}} \times 12\right) - 2$$

We stated this proposed update would modify the scoring methodology for the Ultrafiltration Rate reporting measure so that facilities would be scored based on the number of eligible patient-months, as opposed to facility-months. We explained that the facility-month scoring methodology requires facilities to report every data element necessary to calculate a UFR reporting rate for 100 percent of its eligible patients each month in order to receive any credit for successfully reporting the measure for that month. We stated that the facility-month scoring approach then counts the number of months in the performance period that the facility received credit for reporting over the course of the performance period. For example, under the facility-scoring methodology, if a facility has 10 eligible patients in January, the facility must report all required UFR data elements for each of those 10 patients in order to receive any credit for January reporting. We stated that if the facility only reports the required UFR data elements for 9 of those 10 patients, the facility receives a zero for January. In the CY 2021 ESRD PPS proposed rule, we stated that our concern with this approach is that there may be circumstances, such as when an eligible patient is hospitalized, when facilities cannot obtain UFR data for a single patient, and as a consequence, cannot receive any credit for the data it did report that month (85 FR 42187). When we finalized the Ultrafiltration Rate reporting measure in the CY 2017 ESRD PPS final rule, stakeholders raised their concern regarding this issue (81 FR 77914). At the time, we responded that because we defined the population for this reporting measure by assignment to a facility for a full month, the facility is still required to provide data even in cases where a patient may spend part of that month hospitalized since the data elements are products of ongoing dialysis treatment. We stated that since we do not restrict facilities from coordinating with hospitals to obtain relevant data, we believed that such coordination is appropriate. However, our rationale for this was based on the reporting requirements prescribed by a facility-month definition. Furthermore, we stated that coordinating with hospitals to obtain relevant data continues to be a stakeholder concern in reporting UFR data. In the CY 2021 ESRD PPS proposed rule, we stated our belief that the proposed patient-month scoring methodology is more objective because it scores facilities based on the percentage of eligible patients across the entire performance period for which they report all UFR data elements (85 FR 42187). Thus, if a facility has 100 eligible patients in CY 2020 and reports all data elements necessary to calculate a UFR rate for 90 of them, we stated that the facility will receive a rounded score based on a 90 percent reporting rate. We believe that this methodology will give facilities more flexibility to receive credit for UFR reporting throughout the 12-month performance period.

In the CY 2021 ESRD PPS proposed rule, we stated that the Ultrafiltration Rate reporting measure is intended to guard against risks associated with high ultrafiltration (that is, rapid fluid removal) rates for adult dialysis patients undergoing hemodialysis (HD), because of indications that high ultrafiltration is an independent predictor of mortality. We stated that faster ultrafiltration may lead to a number of health risks resulting from large volumes of fluid removed rapidly during each dialysis session, with deleterious consequences for the patient both in the short and longer term. The outcome of this reporting measure is the documentation of the ultrafiltration measurements, which ultimately contributes to the quality of the patient's ESRD treatment. We stated that we believe that calculating the measure rates using the patient-month scoring methodology better supports our goal of assessing performance on whether the facility is documenting UFR for its eligible patients, which we believe will lead to better patient-level outcomes (85 FR 42187).

We also stated our belief that this change is consistent with our plan to re-evaluate our reporting measures for opportunities to more closely align them with NQF measure specifications (see 84 FR 60724). We stated that we believe that this proposed change would make the Ultrafiltration Rate reporting measure more consistent with the NQF measure upon which it is based, Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hr) (NQF #2701), which reports results using a ''patient-month'' construction. Although we stated that we recognize that both the Anemia Management reporting measure and the Serum Phosphorus reporting measure are also calculated using a facility-month construction, we stated that we were not proposing to change the scoring methodology used for either of those measures because both measures are finalized for removal beginning with the PY 2021 ESRD QIP (83 FR 56986 through 56989). We stated that the proposed update to the UFR reporting measure scoring methodology will make the scoring methodology for that measure consistent with the scoring methodology we are using to calculate the Medication Reconciliation (MedRec) reporting measure (83 FR 57011). We stated that we also believed that the utilization of this patient-month scoring methodology for both the MedRec and the Ultrafiltration Rate reporting measures better reflects our intent to score facilities based on actions taken by the facility that impact patient experiences.

We sought comment on this proposal.

The comments on our proposal to update the scoring methodology for the Ultrafiltration Rate reporting measure and our responses to those comments are set forth below.

Comment: Several commenters expressed support for the proposal to change the Ultrafiltration Rate reporting measure's scoring methodology from facility-months to patient-months. Several commenters expressed appreciation that the ''patient-months'' construction aligns with the NQF's Ultrafiltration Rate measure specifications. A few commenters expressed support for the proposed

update to the Ultrafiltration Rate reporting measure to use patient-months because it would ensure the reliability of measure score calculations and thus enable CMS to better evaluate facility performance. A few commenters expressed support for the proposed update to the Ultrafiltration Rate reporting measure, believing that it would help address difficulties with measure requirements where all data on all patients had to be included in order to receive credit for reporting each month. One commenter stated that the proposed update would score facilities based on actions that impact patient care and appreciated the move away from ''all or nothing'' requirements.

Response: We thank the commenters for their support. We agree that the proposed methodology is more outcomes focused, and better supports our goal of assessing performance on whether the facility is documenting UFR for its eligible patients, which we believe will lead to better patient-level outcomes. We also agree that the proposed update will give facilities more flexibility to receive credit for UFR reporting throughout the 12-month performance period.

Comment: One commenter expressed support for the proposed update to the Ultrafiltration Rate reporting measure, but also stated that it would like to work with CMS on developing an outcome measure that better assesses quality of care for ultrafiltration.

Response: We thank the commenter for its support and continue to welcome feedback on ways to improve measures in the program.

Comment: A few commenters expressed concern that the Ultrafiltration Rate reporting measure may penalize facilities that are unable to comply with reporting requirements due to circumstances beyond their control, such as patient non-compliance due to hospitalization or missed treatments.

Response: We thank the commenters for their feedback. Under the current facility-month scoring methodology, a facility is required to report every data element necessary to calculate a UFR reporting rate for 100 percent of its eligible patients each month in order to receive any credit for successfully reporting the measure for that month. We believe the update to the Ultrafiltration Rate reporting measure's scoring methodology addresses situations in which facilities may experience challenges collecting data when patients are hospitalized or miss treatments because it does not require 100 percent reporting for all patients. We believe that the patient-months construction gives facilities more flexibility to receive credit for UFR reporting throughout the performance period because it scores a facility based on the facility reporting all UFR data elements for eligible patients across the entire performance period, and does not require reporting for all eligible patients each month in order to receive the maximum score on the measure.

Final Rule Action: After considering the comments we received, we are finalizing our proposal to update the scoring methodology for the Ultrafiltration Rate reporting measure as proposed, beginning with PY 2023.

4. Eligibility Requirements for the PY 2023 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 10. We did not propose any changes to these eligibility requirements for the PY 2023 ESRD QIP.

TABLE 10—ELIGIBILITY REQUIREMENTS FOR SCORING ON ESRD QIP MEASURES

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
VAT: Long-term Catheter Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
VAT: Standardized Fistula Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11–25 qualifying patients.
NHSN Dialysis Event (Reporting)	11 qualifying patients	N/A	11–25 qualifying patients.
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
STrR (Reporting)	10 patient-years at risk	N/A	10–21 patient-years at risk.
SHR (Clinical)	5 patient-years at risk	N/A	5–14 patient-years at risk.
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before October 1 prior to the performance period that applies to the program year.	N/A.
Depression Screening and Follow-Up (Reporting).	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A.
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A.
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A.
PPPW (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.

5. Clarification of the Timeline for Facilities To Make Changes to Their NHSN Bloodstream Infection (BSI) Clinical Measure and NHSN Dialysis Event Reporting Measure Data for Purposes of the ESRD QIP

In the CY 2021 ESRD PPS proposed rule (85 FR 42188), we stated that under our current policy for the NHSN BSI clinical measure and NHSN Dialysis Event reporting measure, facilities are required to submit monthly data on a quarterly basis, and each quarter's data is due 3 months after the end of the quarter (81 FR 77879 through 77881). As an example, we stated that data collected by facilities between January 1 and March 31, 2021 is due to NHSN by June 30, 2021, data collected between April 1 and June 30, 2021 is due to NHSN by September 30, 2021, and data collected between July 1 and September 30, 2021 is due to NHSN by December 31, 2021. We further noted that after each quarterly data submission deadline, the Centers for Disease Control and Prevention (CDC) takes a snapshot of the facility's data for the quarter and creates a permanent data file. Each quarterly permanent data file is aggregated together to create the annual CMS ESRD QIP Final Compliance File, which the CDC transmits to CMS for purposes of determining whether the facility has met the reporting requirements for these measures. We also noted that facilities may make changes to their quarterly NHSN data for purposes of the ESRD QIP at any point up until the applicable quarterly submission data deadline (85 FR 42188).

In the CY 2021 ESRD PPS proposed rule (85 FR 42188), we stated that we have become aware that the NHSN system does not prevent facilities from making changes to their data for purposes of CDC surveillance after the applicable ESRD QIP quarterly submission deadline has passed. We also clarified that any changes that a facility makes to its data after the ESRD QIP deadline that applies to those data will not be included in the quarterly permanent data file that the CDC generates for purposes of creating the annual CMS ESRD QIP Final Compliance File. As we noted in the proposed rule, each quarterly permanent data file captures a snapshot of the facility's data as of the quarterly submission deadline, and that file cannot be updated for purposes of the ESRD QIP because of operational and timing issues.

We received a few comments on this clarification.

Comment: A few commenters expressed support for the clarification of the timeline for facilities to make changes to NHSN Dialysis Event and the NHSN BSI measure data. One commenter expressed support for the clarification, noting the importance of providing accurate information about bloodstream infections to patients and caregivers.

Response: We thank the commenters for their support.

6. Payment Reduction Scale for the PY 2023 ESRD QIP

Under our current policy, a facility will not receive a payment reduction for a payment year in connection with its performance for the ESRD QIP if it achieves a total performance score (TPS) that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at § 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

Our current policy, which is codified at § 413.177 of our regulations, is also to implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the minimum TPS (76 FR 634 through 635).

In the CY 2021 ESRD PPS proposed rule (85 FR 42189), for PY 2023 we estimated based on available data that a facility must meet or exceed a mTPS of 57 in order to avoid a payment reduction. We noted that the mTPS estimated in the CY 2021 ESRD PPS proposed rule was based on data from CY 2018 instead of the PY 2023 baseline period (CY 2019) because CY 2019 data were not yet available.

We refer readers to Table 8 of this final rule for the PY 2023 finalized performance standards for each clinical measure. We stated in the CY 2021 ESRD PPS proposed rule that under our current policy, a facility that achieves a TPS below 57 would receive a payment reduction based on the TPS ranges indicated in Table 9 (85 FR 42189). Table 11 of this final rule, is a reproduction of Table 9 from the CY 2021 ESRD PPS proposed rule.

TABLE 11—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2023 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–57	0
56–47	0.5
46–37	1.0
36–27	1.5
26–0	2.0

We stated our intention to update the mTPS for PY 2023, as well as the payment reduction ranges for that payment year, in the CY 2021 ESRD PPS final rule.

We have now finalized the payment reductions that will apply to the PY 2023 ESRD QIP using updated CY 2019 data. The mTPS for PY 2023 will be 57, and the finalized payment reduction scale is shown in Table 12.

TABLE 12—FINALIZED PAYMENT REDUCTION SCALE FOR PY 2023 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–57	0
56–47	0.5
46–37	1.0
36–27	1.5
26–0	2.0

7. Reduction of the Number of Records That a Facility Selected for NHSN Validation Must Submit

In the CY 2021 ESRD PPS proposed rule (85 FR 42189), we stated that one of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP currently includes two validation studies for this purpose: The Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) data validation study (OMB Control Number 0938–1289) and the NHSN validation study (OMB Control Number 0938–1340). In the CY 2019 ESRD PPS final rule, we adopted the CROWNWeb data validation study as a permanent feature of the Program (83 FR 57003). Under that policy, we will continue validating CROWNWeb data in PY 2023 and subsequent payment years, and we will deduct 10 points from a facility's TPS if it is selected for validation but does not submit the requested records.

We also adopted a methodology for the PY 2022 NHSN validation study, which targets facilities for NHSN

validation by identifying facilities that are at risk for under-reporting. For additional information on this methodology, we referred readers to the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767). In the CY 2020 ESRD PPS final rule, we finalized our proposal to continue using this methodology for the NHSN validation study for PY 2023 and subsequent years (84 FR 60727). In that rule, we concluded that to achieve the most reliable results for a payment year, we would need to review approximately 6,072 charts submitted by 303 facilities, and that this sample size would produce results with a 95 percent confidence level and a 1 percent margin of error. Based on those results and to ensure that dialysis event data reported to the NHSN for purposes of the ESRD QIP are accurate, we finalized our proposal to continue use of this methodology in the PY 2023 NHSN validation study and for subsequent years.

Additionally, as we had previously finalized for CROWNWeb validation, we finalized our proposal to adopt NHSN validation as a permanent feature of the ESRD QIP with the methodology we first finalized for PY 2022 and are continuing for PY 2023 and subsequent years. We stated that we continued to believe that the purpose of our validation programs is to ensure the accuracy and completeness of data that are scored under the ESRD QIP, and that we believed that validating NHSN data using this methodology achieves that goal.

In the CY 2019 ESRD PPS final rule, we finalized that a sample of 300 facilities will be selected for the NHSN validation study each year, and that each facility will be required to submit 20 patient records per quarter for each of the first two quarters of the calendar year (83 FR 57001), for a total of 40 records. In the CY 2021 ESRD PPS proposed rule (85 FR 42189 through 42190), we proposed to change this requirement and allow facilities selected to participate in the NHSN validation study to submit a total of 20 patient records for the applicable calendar year. We also proposed to allow facilities to submit patient records from any two quarters during the year, as long as all of the records are from no more than two quarters. For example, we stated that a facility could choose to submit two records from Q1 and 18 records from Q4, or six records from Q2 and 14 records from Q3, but it could not submit four records from Q1, eight records from Q2, and eight records from Q3.

We stated that we had concluded this revised approach would reduce facility burden by decreasing the required number of patient records and allowing more flexibility for facilities to choose what records to submit, while continuing to maintain a sample size that is adequate for our validation analysis. In reaching this conclusion, we stated that we had been informed by the CDC's recommendations. We stated that based on the sample estimation analysis, the CDC recommended the following factors to improve the precision of estimation of accuracy of dialysis events reported to NHSN: An expected 80 percent of dialysis events reporting accuracy from facilities and setting the precision of the NHSN validation study to a 95 percent confidence level and 1 percent margin of error, which would require a total of 6,072 chart reviews. Beginning with the CY 2017 and CY 2018 NHSN dialysis validation, we stated that we have gradually increased the number of facilities randomly selected for validation, as well as the number of charts for review, in order to achieve the 6,000 chart threshold necessary for an accurate review. Initially, 35 facilities were randomly selected and 10 charts per facility were reviewed. For CY 2019, 150 facilities were randomly selected and each facility submitted a total of 20 records, to achieve the total of 3,000 charts available for review. For CY 2020, the goal was to increase from 150 to 300 facilities, where each facility would submit a total of 20 records thereby achieving the total of 6,000 charts available for review, as we had previously finalized (83 FR 57001). Because a total of 20 records would achieve the 6,000 chart threshold necessary for an accurate review, we stated that we had concluded that we could reduce the sample size from 40 records to 20 records. We stated that we believed a total of 20 medical records across a 6-month validation study time frame for a calendar year, rather than 20 records per quarter would provide a sufficiently accurate sample size.

In the CY 2021 ESRD PPS proposed rule, we stated our belief that the reduction in patient records still provides an adequate sample size for the validation and reduces overall facility burden (85 FR 42190). We also stated that a recent estimation analysis conducted by the CDC supports our belief that a review of 20 charts per facility across a specified validation timeline that are acquired by randomly selecting approximately 300 facilities would continue to meet the medical record selection criteria outlined in the NHSN Dialysis Validation methodology. We stated that this would meet the CDC's recommended sample estimate to achieve the 95 percent confidence level precision and 1 percent margin of error, while also reducing facility burden.

We sought comments on this proposal.

The comments on our proposal to reduce the number of records that a facility selected for NHSN validation must submit and our responses to those comments are set forth below. We did not propose any changes to the CROWNWeb validation study methodology.

Comment: Several commenters expressed support for the proposal to reduce the number of patient records required for submission for the NHSN validation study. Several commenters noted that the proposed update will reduce provider burden. A few commenters noted that the proposed 20 patient records requirement is an adequate sample size for validation.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to update the records submission requirements for the NHSN data validation study as proposed, beginning with PY 2023.

D. Updates for the PY 2024 ESRD QIP

1. Continuing Measures for the PY 2024 ESRD QIP

In the CY 2021 ESRD PPS proposed rule (85 FR 42190), we stated that, under our previously adopted policy, the PY 2023 ESRD QIP measure set will also be used for PY 2024. We did not propose to adopt any new measures beginning with the PY 2024 ESRD QIP.

2. Performance Period for the PY 2024 ESRD QIP

In the CY 2021 ESRD PPS proposed rule (85 FR 42190), we stated our continued belief that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. In the CY 2020 ESRD PPS final rule, we finalized the performance and baseline periods for the PY 2023 ESRD QIP (84 FR 60728). We also finalized our proposal to adopt automatically a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year. Under this policy, CY 2022 will be the performance period and CY 2020 will be the baseline period for the PY 2024 ESRD QIP.

3. Performance Standards for the PY 2024 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish

performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We recently codified definitions for the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

a. Performance Standards for Clinical Measures in the PY 2024 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we do not have CY 2020 data. In the CY 2021 ESRD PPS proposed rule, we stated our intent to publish these numerical values, using CY 2020 data, in the CY 2022 ESRD PPS final rule (85 FR 42190). However, we acknowledge that CY 2020 data may be impacted by the nationwide Extraordinary Circumstances Exception (ECE) we granted to facilities in response to the COVID–19 PHE, which excluded data from the first and second quarter of CY 2020. We are considering ways to address this and will provide further guidance in the CY 2022 ESRD PPS proposed rule.

b. Performance Standards for the Reporting Measures in the PY 2024 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and Follow-Up reporting measure, the Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure (83 FR 57010 through 57011). In the CY 2021 ESRD PPS proposed rule (85 FR 42190), we stated that we will continue use of these performance standards in PY 2024.

4. Scoring the PY 2024 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at § 413.178(e).

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at § 413.178(e), and more information on our scoring policy for reporting measures can be found in the CY 2020 ESRD PPS final rule (84 FR 60728). We previously finalized policies for scoring performance on the NHSN Dialysis Event reporting measure in the CY 2018 ESRD PPS final rule (82 FR 50780 through 50781), as well as policies for scoring the Ultrafiltration Rate reporting measure, MedRec reporting measure, and Clinical Depression Screening and Follow-up reporting measure in the CY 2019 ESRD PPS final rule (83 FR 57011). We also previously finalized the scoring policy for the STrR reporting measure in the CY 2020 ESRD PPS final rule (84 FR 60721 through 60723). In section IV.C.3 of this final rule, we finalized our proposal to use patient-months instead of facility-months when scoring the Ultrafiltration Rate reporting measure.

5. Weighting the Measure Domains and the TPS for PY 2024

Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of the TPS, the Care Coordination Measure Domain a weight of 30 percent of the TPS, the Clinical Care Measure Domain a weight of 40 percent of the TPS, and the Safety Measure domain a weight of 15 percent of the TPS.

In the CY 2019 ESRD PPS final rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures (83 FR 57011 through 57012). In the CY 2020 ESRD PPS final rule, we finalized a policy to use the measure weights we finalized for PY 2022 for the PY 2023 ESRD QIP and subsequent payment years, and also to use the PY 2022 measure weight redistribution policy for the PY 2023 ESRD QIP and subsequent payment years (84 FR 60728 through 60729). We did not propose any updates to these policies. Under our current policy, a facility must be eligible to be scored on at least one measure in two of the four measures domains in order to be eligible to receive a TPS (83 FR 57012).

V. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, 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. We solicited comments in the proposed rule, which published in the **Federal Register** on July 13, 2020 (85 FR 42132 through 42208). For the purpose of transparency, we are republishing the discussion of the information collection requirements. All of the requirements discussed in this section are already accounted for in OMB approved information requests.

B. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text. However, this final rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP-Wage Estimates

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to CROWNWeb and NHSN, as well as compiling and submitting patient records for purpose of the data validation studies, rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients. We stated that the median hourly wage of a Medical Records and Health Information Technician is $20.50 per hour.[210] We also stated that fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimated an hourly labor cost of $41.00 as the basis of the wage estimates for all collections of information calculations in the ESRD

[210] *https://www.bls.gov/oes/current/oes292098.htm.*

QIP. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. We stated that these are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, we stated that there is no practical alternative and we believe that these are reasonable estimation methods.

We used this updated wage estimate, along with updated facility and patient counts to re-estimate the total information collection burden in the ESRD QIP for PY 2023 that we discussed in the CY 2020 ESRD QIP final rule (84 FR 60787 through 60788) and to estimate the total information collection burden in the ESRD QIP for PY 2024. We provided the re-estimated information collection burden associated with the PY 2023 ESRD QIP and the newly estimated information collection burden associated with the PY 2024 ESRD QIP in sections IV.D.2 and IV.D.3 of this final rule.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2023 and PY 2024

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. In this final rule, we are updating these estimates using a newly available wage estimate of a Medical Records and Health Information Technician. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff will submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year will be approximately $30,750 (750 hours × $41.00), or an annual total of approximately $102.50 ($30,750/300 facilities) per facility in the sample. The decrease in our burden estimate is due to using the median hourly wage instead of the mean hourly wage for Medical Records and Health Information Technicians or similar staff and is not the result of any policies finalized in this final rule. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1289).

In section IV.C.7 of this final rule, we finalized our proposal to reduce the number of records that a facility selected to participate in the NHSN data validation study must submit to a CMS contractor, beginning with PY 2023. Under this finalized policy, a facility is required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this policy is the time and effort necessary to submit the requested records to a CMS contractor. Applying our policy to reduce the number of records required from each facility participating in the NHSN validation study, we estimate that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are asked to submit records each year, we estimate that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities × 5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar staff would submit these data, using the newly available wage estimate of a Medical Records and Health Information Technician, we estimate that the aggregate cost of the NHSN data validation each year would be approximately $61,500 (1,500 hours × $41), or a total of approximately $205 ($61,500/300 facilities) per facility in the sample. The reduction in our burden estimate is due to a reduction in the number of medical records collected and the utilization of the median hourly wage instead of the mean hourly wage. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1340).

3. CROWNWeb Reporting Requirements for PY 2023 and PY 2024

To determine the burden associated with the CROWNWeb reporting requirements, we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to CROWNWeb for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into CROWNWeb, and the number of facilities submitting data to CROWNWeb. In the CY 2020 ESRD PPS final rule, we estimated that the burden associated CROWNWeb reporting requirements for the PY 2023 ESRD QIP was approximately $211 million (84 FR 60651).

We did not propose any changes that would affect the burden associated with CROWNWeb reporting requirements for PY 2023 or PY 2024. However, we have re-calculated the burden estimate for PY 2023 using updated estimates of the total number of dialysis facilities, the total number of patients nationally, and wages for Medical Records and Health Information Technicians or similar staff as well as a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. We note that the burden estimate for PY 2023 has been updated from the estimates in the CY 2021 ESRD PPS proposed rule due to updated information about the total number of facilities participating in the ESRD QIP and the total number of patients. In the CY 2020 ESRD PPS final rule, we estimated that the amount of time required to submit measure data to CROWNWeb was 2.5 minutes per element and used a rounded estimate of 0.042 hours in our calculations (84 FR 60788). In this final rule, we did not use a rounded estimate of the time needed to complete data entry for CROWNWeb reporting. There are 229 data elements for 532,931 patients across 7,610 facilities. At 2.5 minutes per element, this yields approximately 668.21 hours per facility. Therefore, the PY 2023 burden is 5,085,050 hours (668.21 hours × 7,610 facilities). (Using the wage estimate of a Medical Records and Health Information Technician, we estimate that the PY 2023 total burden cost is approximately $208 million (5,085,050 hours × $41). There is no net incremental burden change from PY 2023 to PY 2024 because we are not changing the reporting requirements for PY 2024.

VI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory

Review, the Regulatory Flexibility Act (RFA) (Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, the Congressional Review Act (5 U.S.C. 801 *et seq.*), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs.

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule has been designated by the Office of Information and Regulatory Affairs as an economically significant rule as measured by the $100 million threshold, and hence also been designated as a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

We solicited comments on the regulatory impact analysis provided. With regard to the ESRD PPS, we did not receive any comments on the RIA.

2. Statement of Need

a. ESRD PPS

This rule finalizes a number of routine updates and several policy changes to the ESRD PPS for CY 2021. The routine updates include the CY 2021 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2021 for renal dialysis services furnished to ESRD beneficiaries.

b. AKI

This rule also finalizes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2021 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

This final rule finalizes updates to the ESRD QIP beginning with PY 2023, including a modification to the scoring methodology for the Ultrafiltration Rate reporting measure and an update to the reporting requirements for facilities selected for NHSN data validation. This final rule also clarifies the review and correction timeline for the NHSN BSI clinical measure and NHSN Dialysis Event reporting measure.

3. Overall Impact

a. ESRD PPS

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $250 million in payments to ESRD facilities in CY 2021, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, adoption of the 2018 OMB delineations with a transition period, and including calcimimetics in the ESRD PPS base rate. These figures do not reflect estimated increases or decreases in expenditures based on our expansion of eligibility for the TPNIES to certain new and innovative home dialysis machines when used in the home for a single patient. The fiscal impact of this policy cannot be determined due to the uniqueness of each new and innovative home dialysis machine and its cost.

b. AKI

We estimate that the updates to the AKI payment rate would result in an increase of approximately $4 million in payments to ESRD facilities in CY 2021.

c. ESRD QIP

For PY 2023, we have re-estimated the costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of dialysis facilities, the total number of patients nationally, wages for Medical Records and Health Information Technicians or similar staff, and a refined estimate of the number of hours needed to complete data entry for CROWNWeb reporting. We note that the estimated costs have been updated from the estimates in the CY 2021 ESRD PPS proposed rule due to updated information about the total number of facilities participating in the ESRD QIP and the total number of patients. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the CROWNWeb validation study and CROWNWeb reporting. We updated the annual burden associated with the NHSN validation study to reflect our new policy to reduce the total number of records collected. The finalized updates will reduce the collection of information requirements associated with the NHSN validation study by $65,460 per year across the facilities selected for validation that year.

We also finalized the payment reduction scale using more recent data for the measures in the ESRD QIP measure set and applying our finalized proposal to modify the scoring methodology for the Ultrafiltration Rate reporting measure beginning with the PY 2023 ESRD QIP. We estimate approximately $208 million in information collection burden, which includes the cost of complying with this rule, and an additional $16 million in estimated payment reductions across all facilities for PY 2023.

For PY 2024, we estimate that the finalized revisions to the ESRD QIP would result in $208 million in information collection burden, and $16 million in estimated payment reductions across all facilities, for an impact of $224 million as a result of the policies we have previously finalized and the policies we have finalized in this final rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the CY 2021 ESRD PPS proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that

not all commenters reviewed CY 2021 ESRD PPS proposed rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2021 ESRD PPS 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 also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption in the CY 2021 ESRD PPS proposed rule but did not receive comments.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health services managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 6.25 hours for the staff to review half of this final. For each entity that reviews the rule, the estimated cost is $692.13 (6.25 hours × $110.74). Therefore, we estimate that the total cost of reviewing this regulation rounds to $81,671. ($692.13 × 118 reviewers).

B. Detailed Economic Analysis

1. CY 2021 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2020 to estimated payments in CY 2021. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2020 and CY 2021 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2019 data from the Part A and Part B Common Working Files as of July 31, 2020, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2019 claims to 2020 and 2021 using various updates. The updates to the ESRD PPS base rate are described in section II.B.4.d of this final rule. Table 13 shows the impact of the estimated CY 2021 ESRD PPS payments compared to estimated payments to ESRD facilities in CY 2020.

TABLE 13—IMPACT OF FINALIZED CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2021

Facility type	Number of facilities (A)	Number of treatments (in millions) (B)	Effect of 2021 changes in outlier policy (C) %	Effect of changes in wage index data (D) %	Effect of CBSA change & 5% cap policy (E) %	Effect of bundling calcimimetics into base rate (F) %	Effect of change for payment rate update (G) %	Effect of total 2021 proposed changes (H) %
All Facilities	7,659	45.3	0.4	0.0	0.0	−0.1	1.6	2.0
Type:								
Freestanding	7,270	43.5	0.4	0.0	0.0	0.0	1.6	2.0
Hospital based	389	1.8	0.9	0.1	0.1	−2.9	1.6	−0.2
Ownership Type:								
Large dialysis organization	5,890	35.3	0.4	0.0	0.0	0.9	1.6	2.9
Regional chain	956	5.8	0.3	−0.1	−0.1	−3.7	1.6	−1.9
Independent	509	2.9	0.5	0.3	0.3	−2.6	1.6	0.0
Hospital based [1]	302	1.4	0.9	0.1	0.2	−2.6	1.6	0.2
Unknown	2	0.0	1.5	0.0	−0.1	1.3	1.6	4.4
Geographic Location: [2] [3]								
Rural	1,292	6.5	0.4	0.1	−1.2	0.1	1.6	1.0
Urban	6,367	38.8	0.4	0.0	0.2	−0.1	1.6	2.1
Census Region:								
East North Central	1,223	6.0	0.5	0.1	−0.1	0.5	1.6	2.6
East South Central	606	3.3	0.4	0.0	0.0	−0.8	1.6	1.1
Middle Atlantic	852	5.4	0.5	0.5	0.2	−0.7	1.6	2.1
Mountain	423	2.4	0.3	−0.5	−0.1	1.0	1.6	2.4
New England	203	1.4	0.4	−0.7	−0.1	0.2	1.6	1.4
Pacific [4]	922	6.5	0.4	−0.1	0.1	0.6	1.6	2.5
Puerto Rico and Virgin Islands	52	0.3	0.3	0.1	−0.1	1.1	1.6	2.9
South Atlantic	1,758	10.8	0.5	0.0	0.0	−0.6	1.6	1.4
West North Central	514	2.3	0.6	−0.4	−0.1	0.5	1.6	2.2
West South Central	1,106	6.7	0.4	0.0	0.0	−0.4	1.6	1.6
Facility Size:								
Less than 4,000 treatments	1,377	2.2	0.5	0.0	0.0	0.5	1.6	2.7
4,000 to 9,999 treatments	2,999	12.8	0.5	0.0	−0.1	0.0	1.6	2.1
10,000 or more treatments	3,261	30.2	0.4	0.0	0.0	−0.2	1.6	1.9
Unknown	22	0.1	0.5	0.1	−0.1	−3.4	1.6	−1.3
Percentage of Pediatric Patients:								
Less than 2%	7,551	45.0	0.4	0.0	0.0	−0.1	1.6	1.9
Between 2% and 19%	37	0.3	0.4	0.2	−0.1	−0.5	1.6	1.6
Between 20% and 49%	16	0.0	0.4	−0.3	0.0	3.1	1.6	4.9
More than 50%	55	0.0	0.3	0.0	−0.1	3.8	1.6	5.6

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2] Facility counts for Urban/Rural uses 2021 CBSA delineation. Under 2020 and previous CBSA delineation, facility counts for urban and rural are 6,355 and 1,304 respectively. For payment percent change columns, appropriate definition of Urban/Rural is used.
[3] The 1.2 percent drop in total payments among rural facilities (and increase in total payments among urban facilities) is mostly due facilities shifting from rural to urban status under new CBSA delineation. Controlling for old-CBSA urban/rural status, the change in payment is close to 0 percent.
[4] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.B.4.c of this final rule is shown in column C. For CY 2021, the impact on

all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.4 percent increase in estimated payments. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2021 payments as a result of the final outlier policy changes.

Column D shows the effect of the annual update to the wage index, as described in section II.B.4.b of this final rule. That is, this column reflects the update from the CY 2020 ESRD PPS wage index using older OMB delineations with a basis of the FY 2021 pre-floor, pre-reclassified IPPS hospital wage index data in a budget neutral manner. The total impact of this change is 0.0 percent, however, there are distributional effects of the change among different categories of ESRD facilities. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.7 percent decrease to a 0.5 percent increase due to the annual update to the ESRD PPS wage index.

Column E shows the effect of adopting the 2018 OMB delineations and the transition policy as described in sections II.B.4.b.(2) and II.B.4.b.(3), respectively, of this final rule. That is, the impact represented in this column reflects the change from using the older OMB delineations and basing the CY 2021 ESRD PPS wage index on the FY 2021 pre-floor, pre-reclassified IPPS hospital wage index data to the 2018 OMB delineations and a 5 percent cap on wage index decreases in CY 2021, in a budget neutral manner. The total impact of this change is 0.0 percent, however, there are distributional effects of the change among different categories of ESRD facilities. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 1.2 percent decrease to a 0.3 percent increase due to these updates to the ESRD PPS wage index.

Column F shows the effect of the final addition to the ESRD PPS base rate to include calcimimetics as described in section II.B.1 of this final rule. That is, the impact represented in this column reflects the change, under the ESRD PPS, for payment to ESRD facilities for furnishing calcimimetics. Beginning January 1, 2018, ESRD facilities received payment for calcimimetics under the TDAPA policy in § 413.234(c). Under our final policy, beginning January 1, 2021, we will modify the ESRD PPS base rate by adding $9.93 to include calcimimetics and no longer pay for calcimimetics using the TDAPA. In addition, calcimimetics would become outlier eligible services under § 413.237. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 3.7 percent decrease to a 3.8percent increase due to these policy modifications.

Column G shows the effect of the final CY 2021 ESRD PPS payment rate update as described in section II.B.4.a of this final rule. The final ESRD PPS payment rate update is 1.6 percent, which reflects the ESRDB market basket percentage increase factor for CY 2021 of 1.9 percent and the final MFP adjustment of 0.3 percentage point.

Column H reflects the overall impact, that is, the effects of the final outlier policy changes, the final updated wage index and transition policy, the payment rate update, and the addition to the ESRD PPS base rate to include calcimimetics. We expect that overall ESRD facilities would experience a 2.0 percent increase in estimated payments in CY 2021. The categories of types of facilities in the impact table show impacts ranging from a 1.9 percent decrease to a 5.6 percent increase in their CY 2021 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2021, we estimate that the final ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2021 would be approximately $9.3 billion. This estimate takes into account a projected decrease in fee-for-service Medicare dialysis beneficiary enrollment of 8.6 percent in CY 2021.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 2.0 percent overall increase in the final CY 2021 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 2.0percent in CY 2021, which translates to approximately $60 million.

e. Alternatives Considered

(1) Inclusion of Calcimimetics Into the ESRD PPS Bundled Payment

In section II.B.1 of this final rule, we established that beginning January 1, 2021, we will modify the ESRD PPS base rate by adding $9.93 to include calcimimetics and no longer pay for calcimimetics using the TDAPA. In addition, calcimimetics would become ESRD outlier services eligible for outlier payments under § 413.237. With regard to the methodology utilized to calculate the amount to be added the ESRD PPS base rate, for the CY 2021 ESRD PPS proposed rule, we considered using the Medicare expenditures reflecting payments made for the calcimimetics in CYs 2018 and 2019, that is, approximately $2.3 billion and dividing by total treatments furnished in both years to arrive at an amount of $27.08. However, using the most recent calendar quarter of ASP data available to calculate the ASP-based values as the proxy rate incorporates the lower priced generic calcimimetics into the calculation of the amount added for oral calcimimetics. We believe it is appropriate for the ESRD PPS base rate to reflect generic drug manufacturer ASP data since we believe that this aligns with how ESRD facilities would purchase and furnish the oral calcimimetics in the future.

For the final rule, we considered several alternative approaches: (1) Using the most recent 12 months of claims data, which would result in a base rate increase of $11.85; (2) using only 2019 claims data, which would result in a base rate increase of $11.10; and (3) using both CYs 2018 and 2019 claims data, which would result in a base rate increase of $8.52. We believe a robust data set should reflect both the slow uptake of the injectable calcimimetic and the ramping up of utilization of generic oral calcimimetics. We view the use of 18 months as a mid-point between the proposal to use both CYs 2018 and 2019 and the most recent 12 months of claims data, as requested by commenters. Accordingly, we have concluded that using 18 months of claims data resulting in an increase of $9.93 to the base rate is the most appropriate approach.

(2) Expansion of the TPNIES to Capital-Related Assets That Are Home Dialysis Machines When Used in the Home for a Single Patient

In section II.B.3 of this final rule, we expanded the TPNIES policy to allow capital-related assets that are home dialysis machines when used in the home for a single patient to be eligible for the add-on payment adjustment. Then, consistent with the policies finalized last year for other renal dialysis equipment and supplies eligible for the TPNIES, we would pay 65 percent of the pre-adjusted per

treatment amount for a period of 2 years. With regard to the duration of applying the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient, we considered paying the TPNIES for 3 years. However, we believe that the expansion is consistent with the TDAPA and other Medicare fee-for-service add-on payment programs (for example, the IPPS NTAP), and supports innovation for dialysis in the home setting, the President's Executive order on Advancing American Kidney Health, and current HHS initiatives to support home dialysis, while taking into account the potential increase in ESRD PPS expenditures.

(3) CY 2021 ESRD PPS Wage Index

In section II.B.4.b of this final rule, we adopted the 2018 OMB delineations with a transition policy. That is, we are adopting the OMB delineations based on the September 14, 2018 OMB Bulletin No. 18–04 and, to mitigate any potential negative impacts, we applied a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior calendar year. This transition would be phased in over 2 years, such that the estimated reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021 and no cap would be applied to the reduction in the wage index for the second year, CY 2022. With regard to the transition policy, we considered doing a 2-year 50/50 blended wage index approach consistent with the adoption of OMB delineations in the CY 2015 ESRD PPS final rule (79 FR 66142). However, we determined that the 5 percent cap on any decrease policy would be an appropriate transition for CY 2021 as it provides predictability in payment levels from CY 2020 to the upcoming CY 2021 and additional transparency because it is administratively simpler than the 50/50 blended approach.

2. Final Payment for Renal Dialysis Services Furnished to Individuals With AKI

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2020 to estimated payments in CY 2021. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2020 and CY 2021 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2019 data from the Part A and Part B Common Working Files as of July 31, 2020, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2019 claims to 2020 and 2021 using various updates. The updates to the AKI payment amount are described in section III.B of this final rule. Table 14 shows the impact of the estimated CY 2021 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2020.

TABLE 14—IMPACT OF FINAL CHANGES IN PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2021

Facility type	Number of facilities (A)	Number of treatments (in thousands) (B)	Effect of all wage index changes (C) %	Effect of bundling calcimimetics in the ESRD PPS base rate (D) %	Effect of changes in payment rate update (E) %	Effect of total 2021 final changes (F) %
All Facilities	5,141	296.4	−0.1	4.2	1.6	5.7
Type:						
Freestanding	5,013	290.7	−0.1	4.2	1.6	5.7
Hospital based	128	5.7	−0.1	4.2	1.6	5.8
Ownership Type:						
Large dialysis organization	4,280	250.7	−0.1	4.2	1.6	5.7
Regional chain	596	30.0	−0.1	4.2	1.6	5.7
Independent	185	12.1	0.1	4.2	1.6	6.0
Hospital based [1]	80	3.6	0.0	4.2	1.6	5.9
Unknown	0	0.0	0.0	0.0	0.0	0.0
Geographic Location: [2]						
Rural	885	46.3	−0.1	4.2	1.6	5.7
Urban	4,256	250.0	−0.1	4.2	1.6	5.8
Census Region:						
East North Central	892	54.3	0.0	4.2	1.6	5.8
East South Central	408	21.0	−0.2	4.2	1.6	5.6
Middle Atlantic	535	33.1	0.4	4.2	1.6	6.2
Mountain	294	17.4	−0.5	4.2	1.6	5.3
New England	159	8.6	−0.8	4.2	1.6	4.9
Pacific [3]	607	45.8	−0.1	4.2	1.6	5.7
Puerto Rico and Virgin Islands	2	0.0	−0.1	4.2	1.6	5.8
South Atlantic	1,211	68.6	0.0	4.2	1.6	5.8
West North Central	352	14.2	−0.5	4.2	1.6	5.3
West South Central	681	33.2	0.0	4.2	1.6	5.8
Facility Size:						
Less than 4,000 treatments	606	23.2	−0.1	4.2	1.6	5.7
4,000 to 9,999 treatments	2,076	106.6	−0.1	4.2	1.6	5.8
10,000 or more treatments	2,455	166.4	−0.1	4.2	1.6	5.7
Unknown	4	0.2	−0.5	4.2	1.6	5.3
Percentage of Pediatric Patients:						
Less than 2%	5,141	296.4	−0.1	4.2	1.6	5.7

TABLE 14—IMPACT OF FINAL CHANGES IN PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2021—Continued

Facility type	Number of facilities (A)	Number of treatments (in thousands) (B)	Effect of all wage index changes (C) %	Effect of bundling calcimimetics in the ESRD PPS base rate (D) %	Effect of changes in payment rate update (E) %	Effect of total 2021 final changes (F) %
Between 2% and 19%	0	0.0	0.0	0.0	0.0	0.0
Between 20% and 49%	0	0.0	0.0	0.0	0.0	0.0
More than 50%	0	0.0	0.0	0.0	0.0	0.0

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2] Facility counts for Urban/Rural uses 2021 CBSA delineation. Under 2020 and previous CBSA delineation, facility counts for urban and rural are 4,246 and 895 respectively. For payment percent change columns, appropriate definition of Urban/Rural is used.
[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands).

Column C shows the effect of the final CY 2021 wage indices.

Column D shows the effect of the adjustment to the AKI dialysis payment rate that reciprocates the modification to the ESRD PPS base rate for CY 2021, consistent with § 413.372. As discussed in section II.B.1 of this final rule, we modified the ESRD PPS base rate by adding $9.93 to include calcimimetics.

Column E shows the effect of the final CY 2021 ESRD PPS payment rate update. The ESRD PPS payment rate update is 1.6 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2021 of 1.9 percent and the final MFP adjustment of 0.3 percentage point.

Column F reflects the overall impact, that is, the effects of the updated wage index, the final addition to the ESRD PPS base rate, and the payment rate update. We expect that overall ESRD facilities would experience a 5.7 percent increase in estimated payments in CY 2021. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 6.2 percent in their CY 2021 estimated payments.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we updated the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The decision about where the renal dialysis services are furnished is made by the patient and his or her physician. Therefore, this update will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately $56 million would be paid to ESRD facilities in CY 2021 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be responsible for a 20 percent co-insurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring would assist us in developing knowledgeable, data-driven proposals.

3. ESRD QIP

a. Effects of the PY 2023 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we are using to determine a facility's TPS is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2023 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2023, as codified in our regulations at § 413.177.

For the PY 2023 ESRD QIP, we estimate that, of the 7,610 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 24.3 percent or 1,790 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2023. After finalizing our proposal to update the scoring methodology for the Ultrafiltration Rate reporting measure, the total estimated payment reductions for all the 1,790 facilities expected to receive a payment reduction in PY 2023 would decrease from $18,247,083.76 to approximately $15,770,179.33. We note that the total estimated payment reductions for PY 2023 have been updated from the estimates in the CY 2021 ESRD PPS proposed rule due to updated information about the total number of facilities expected to receive a payment reduction. Facilities that do not receive a TPS do not receive a payment reduction.

Table 15 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 15—ESTIMATED DISTRIBUTION OF PY 2023 ESRD QIP PAYMENT REDUCTIONS

Payment reduction (percent)	Number of facilities	Percent of facilities *
0.0	5,590	75.75
0.5	1,329	18.01
1.0	372	5.04
1.5	64	0.87
2.0	25	0.34

* 230 facilities not scored due to insufficient data.

To estimate whether a facility would receive a payment reduction for PY 2023, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 16) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 16. These estimates also incorporate the finalized update to the scoring methodology for the Ultrafiltration Rate reporting measure.

TABLE 16—DATA USED TO ESTIMATE PY 2023 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
SRR	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
SHR	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
PPPW	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
Kt/V Dialysis Adequacy Comprehensive	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
VAT:		
Standardized Fistula Ratio	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
% Catheter	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
Hypercalcemia	Jan 2018–Dec 2018	Jan 2019–Dec 2019.

For all measures except Standardized Hospitalization Ratio (SHR) and Standardized Readmission Ratio (SRR), clinical measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and STrR, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the proposals outlined in sections IV.C and IV.D of this final rule. Facility reporting measure scores were estimated using available data from CY 2019. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2023 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 17 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2023. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2023 ESRD QIP, the actual impact of the PY 2023 ESRD QIP may vary significantly from the values provided here.

TABLE 17—ESTIMATED IMPACT OF QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2023

	Number of facilities	Number of treatments 2019 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,610	44.8	7,380	1,790	−0.16
Facility Type:					
Freestanding	7,224	43.1	7,035	1,684	−0.15
Hospital-based	386	1.8	345	106	−0.25
Ownership Type:					
Large Dialysis	5,809	34.8	5,690	1,194	−0.12
Regional Chain	944	5.7	923	280	−0.21
Independent	534	2.9	491	227	−0.36
Hospital-based (non-chain)	299	1.3	264	85	−0.28
Unknown	24	0.0	12	4	−0.25
Facility Size:					
Large Entities	6,753	40.6	6,613	1,474	−0.13
Small Entities [1]	833	4.3	755	312	−0.33
Unknown	24	0.0	12	4	−0.25

TABLE 17—ESTIMATED IMPACT OF QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2023—Continued

	Number of facilities	Number of treatments 2019 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
Rural Status:					
(1) Yes	1,292	6.5	1,239	180	−0.09
(2) No	6,318	38.4	6,141	1,610	−0.17
Census Region:					
Northeast	1,046	6.7	1,002	251	−0.15
Midwest	1,734	8.3	1,664	424	−0.17
South	3,452	20.6	3,370	877	−0.17
West	1,318	8.7	1,285	199	−0.09
U.S. Territories [2]	60	0.4	59	39	−0.44
Census Division:					
Unknown	8	0.1	8	3	−0.25
East North Central	1,220	6.0	1,172	354	−0.21
East South Central	604	3.3	593	142	−0.13
Middle Atlantic	845	5.4	808	222	−0.17
Mountain	419	2.4	406	61	−0.09
New England	201	1.4	194	29	−0.09
Pacific	899	6.3	879	138	−0.09
South Atlantic	1,746	10.7	1,703	454	−0.17
West North Central	7,610	44.8	7,380	1,790	−0.16
West South Central	7,224	43.1	7,035	1,684	−0.15
U.S. Territories [2]	47	0.3	47	46	−1.57
Facility Size (# of total treatments):	386	1.8	345	106	−0.25
Less than 4,000 treatments	5,809	34.8	5,690	1,194	−0.12
4,000–9,999 treatments	2,644	11.9	2,620	488	−0.11
Over 10,000 treatments	944	5.7	923	280	−0.21
Unknown	534	2.9	491	227	−0.36

[1] Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2] Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

b. Effects of the PY 2024 ESRD QIP on ESRD Facilities

For the PY 2024 ESRD QIP, we estimate that, of the 7,610 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 24.3 percent or 1,790 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2024. The total payment reductions for all the 1,790 facilities expected to receive a payment reduction is approximately $15,770,179.33. We note that the total payment reductions for PY 2024 have been updated from the estimates in the CY 2021 ESRD PPS proposed rule due to updated information about the total number of facilities expected to receive a payment reduction. Facilities that do not receive a TPS do not receive a payment reduction.

Table 18 shows the overall estimated distribution of payment reductions resulting from the PY 2024 ESRD QIP.

TABLE 18—ESTIMATED DISTRIBUTION OF PY 2024 ESRD QIP PAYMENT REDUCTIONS

Payment reduction (percent)	Number of facilities	Percent of facilities *
0.0	5,590	75.75
0.5	1,329	18.01
1.0	372	5.04
1.5	64	0.87
2.0	25	0.34

* Note: 230 facilities not scored due to insufficient data.

To estimate whether a facility would receive a payment reduction in PY 2024, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 18) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 19.

TABLE 19—DATA USED TO ESTIMATE PY 2024 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
SRR	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
SHR	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
PPPW	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
Kt/V Dialysis Adequacy Comprehensive	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
VAT:		
Standardized Fistula Ratio	Jan 2018–Dec 2018	Jan 2019–Dec 2019

TABLE 19—DATA USED TO ESTIMATE PY 2024 ESRD QIP PAYMENT REDUCTIONS—Continued

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
% Catheter	Jan 2018–Dec 2018	Jan 2019–Dec 2019.
Hypercalcemia	Jan 2018–Dec 2018	Jan 2019–Dec 2019.

For all measures except SHR, SRR, and the STrR reporting measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and SRR, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. For the STrR reporting measure, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates the policies outlined in section IV.C and IV.D of this final rule. Facility reporting measure scores were estimated using available data from CY 2019. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2024 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 20 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2024. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are finalizing to use for the PY 2024 ESRD QIP, the actual impact of the PY 2024 ESRD QIP may vary significantly from the values provided here.

TABLE 20—ESTIMATED IMPACT OF QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2024

	Number of facilities	Number of treatments 2019 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,610	44.8	7,380	1,790	−0.16
Facility Type:					
Freestanding	7,224	43.1	7,035	1,684	−0.15
Hospital-based	386	1.8	345	106	−0.25
Ownership Type:					
Large Dialysis	5,809	34.8	5,690	1,194	−0.12
Regional Chain	944	5.7	923	280	−0.21
Independent	534	2.9	491	227	−0.36
Hospital-based (non-chain)	299	1.3	264	85	−0.28
Unknown	24	0.0	12	4	−0.25
Facility Size:					
Large Entities	6,753	40.6	6,613	1,474	−0.13
Small Entities [1]	833	4.3	755	312	−0.33
Unknown	24	0.0	12	4	−0.25
Rural Status:					
(1) Yes	1,292	6.5	1,239	180	−0.09
(2) No	6,318	38.4	6,141	1,610	−0.17
Census Region:					
Northeast	1,046	6.7	1,002	251	−0.15
Midwest	1,734	8.3	1,664	424	−0.17
South	3,452	20.6	3,370	877	−0.17
West	1,318	8.7	1,285	199	−0.09
U.S. Territories [2]	60	0.4	59	39	−0.44
Census Division:					
Unknown	8	0.1	8	3	−0.25
East North Central	1,220	6.0	1,172	354	−0.21
East South Central	604	3.3	593	142	−0.13
Middle Atlantic	845	5.4	808	222	−0.17
Mountain	419	2.4	406	61	−0.09
New England	201	1.4	194	29	−0.09
Pacific	899	6.3	879	138	−0.09
South Atlantic	1,746	10.7	1,703	454	−0.17
West North Central	514	2.3	492	70	−0.09
West South Central	1,102	6.7	1,074	281	−0.17
U.S. Territories [2]	52	0.3	51	36	−0.48
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,315	2.6	1,195	265	−0.18

TABLE 20—ESTIMATED IMPACT OF QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2024—Continued

	Number of facilities	Number of treatments 2019 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
4,000–9,999 treatments	2,803	12.2	2,771	530	−0.12
Over 10,000 treatments	3,246	29.7	3,240	961	−0.18
Unknown	246	0.3	174	34	−0.16

[1] Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2] Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

c. Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as dialysis facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

d. Effects on the Medicare Program

For PY 2024, we estimate that the ESRD QIP would contribute approximately $15,770,179.33 in Medicare savings. For comparison, Table 21 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2024.

TABLE 21—ESTIMATED PAYMENT REDUCTIONS PAYMENT YEARS 2018 THROUGH 2024

Payment year	Estimated payment reductions
PY 2024	$15,770,179.33.
PY 2023	15,770,179.33.
PY 2022	18,247,083.76 (84 FR 60794).
PY 2021	32,196,724 (83 FR 57062).
PY 2020	31,581,441 (81 FR 77960).
PY 2019	15,470,309 (80 FR 69074).
PY 2018	11,576,214 (79 FR 66257).

e. Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's inception, there is evidence on improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

f. Alternatives Considered

In section IV.C.7 of this final rule, we finalized our policy that facilities selected to participate in the NHSN data validation study can submit a total of 20 records across two quarters. In the CY 2021 ESRD PPS proposed rule, we stated that we considered retaining our current reporting requirement, under which facilities must submit 20 records per quarter for each of the first two quarters of the CY, for a total of 40 records (85 FR 42204). However, we concluded that the reduction in patient records provides an adequate sample size for the validation. After considering public comments, we finalized this approach in this final rule because we believe that it will lower administrative costs and will reduce the burden on facilities.

C. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 22, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

TABLE 22—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS

Category	Transfers
ESRD PPS and AKI (CY 2021)	
Annualized Monetized Transfers.	$190 million.
From Whom to Whom	Federal Government to ESRD providers.
Increased Beneficiary Co-insurance Payments.	$60 million.
From Whom to Whom	Beneficiaries to ESRD providers.
ESRD QIP for PY 2023	
Annualized Monetized Transfers.	−$16 million.
From Whom to Whom	Federal Government to ESRD providers.
ESRD QIP for PY 2024	
Annualized Monetized Transfers.	−$16 million.
From Whom to Whom	Federal Government to ESRD providers.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

D. Regulatory Flexibility Act Analysis (RFA)

The Regulatory Flexibility Act requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities

include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 11 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $41.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's website at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as 621492 with a size standard of $41.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 13. Using the definitions in this ownership category, we consider 509 facilities that are independent and 302 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by Large Dialysis Organizations (LDOs) and regional chains would have total revenues of more than $41.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates finalized in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 0.2 percent increase in payments for CY 2021. An independent facility (as defined by ownership type) is estimated to receive no update in payments for CY 2021.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $56 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 1,790 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2024 ESRD QIP, 267 are ESRD small entity facilities. We present these findings in Table 18 (''Estimated Distribution of PY 2024 ESRD QIP Payment Reductions'') and Table 20 (''Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2024''). We note that these estimates have been updated from the CY 2021 ESRD PPS proposed rule due to updated information about both the total number of facilities and the total number of small entity facilities expected to receive a payment reduction. We estimate that the payment reductions would average approximately $9,770.87 per facility across the 1,790 facilities receiving a payment reduction, and $10,748.02 for each small entity facility. We also estimate that there are 833 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities would decrease 0.33 percent in CY 2024.

Therefore, the Secretary has determined that this final rule would not have a significant economic impact on a substantial number of small entities. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We solicited comment on the RFA analysis provided. We received no comments on this section.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 126 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 126 rural hospital-based dialysis facilities would experience an estimated 0.2 percent decrease in payments.

Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This final rule does not mandate any requirements for state, local, or tribal governments in the aggregate, or by the private sector. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of states, local or tribal governments.

G. Regulatory Reform Under Executive Order 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs was issued on January 30, 2017. It has been determined that this is a transfer rule, which imposes no more than *de minimis* costs. As a result, this rule is not considered a regulatory or deregulatory action under Executive Order 13771.

H. Congressional Review Act

This final 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.*) and has been transmitted to the Congress and the Comptroller General for review.

VII. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and is posted on the CMS website at *http://www.cms.gov/ESRDPayment/PAY/list.asp.* In addition to the Addenda, limited data set files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html.* Readers who experience any problems accessing the Addenda or LDS files, should contact *ESRDPayment@cms.hhs.gov.*

List of Subjects in 42 CFR Part 413

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.232 is amended by—

■ a. Revising paragraphs (b) introductory text, (b)(1), (e), and (g) introductory text; and

■ b. Adding paragraphs (g)(4) and (h).

The revisions and additions read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (g) of this section:

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of this section) preceding the payment year; and

* * * * *

(e) Except as provided in paragraph (f) of this section and unless extraordinary circumstances justify an exception, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor (MAC) that the facility meets all the criteria established in this section, except that:

(1) For payment year 2012, the attestation must be provided by January 3, 2012;

(2) For payment year 2015, the attestation must be provided by December 31, 2014;

(3) For payment year 2016, the attestation must be provided by December 31, 2015; and

(4) For payment year 2021, the attestation must be provided by December 31, 2020.

* * * * *

(g) To receive the low-volume adjustment, an ESRD facility must include in their attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraph (g)(4) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

* * * * *

(4) For payment years 2021, 2022, and 2023, the attestation specified in paragraph (e)(4) of this section must indicate that the ESRD facility meets all the criteria specified in this section, except that, for a facility that would not otherwise meet the number of treatments criterion specified in paragraph (b)(1) of this section because of the COVID–19 PHE, the facility may attest that it furnished less than 2,000 treatments in any six months during the cost-reporting period ending in 2020. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the payment year due to temporary patient shifting as a result of the COVID–19 PHE; and

(ii) The MAC relies on the attestation and multiplies the total number of treatments for the 6-month period by 2.

(h) When an ESRD facility provides an attestation in accordance with paragraph (e) of this section, for the third eligibility year, the MAC verifies the as-filed cost report and takes one of the following actions:

(1) If the MAC determines an ESRD facility meets the definition of a low-volume facility as described in paragraph (b) of this section, CMS adjusts the low-volume facility's base rate for the entire payment year; or

(2) If the MAC determines an ESRD facility does not meet the definition of a low-volume facility as described in paragraph (b) of this section, the MAC reprocesses claims and recoups low-volume adjustments paid during the payment year.

■ 3. Section 413.234 is amended by adding paragraph (f) to read as follows:

§ 413.234. Drug designation process.

* * * * *

(f) *Methodology for modifying the ESRD PPS base rate to account for the costs of calcimimetics in the ESRD PPS bundled payment.* Beginning January 1, 2021, payment for calcimimetics is included in the ESRD PPS base rate using the following data sources and methodology:

(1) The methodology specified in paragraph (f)(2) of this section for determining the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate uses the following data sources:

(i) Total units of oral and injectable calcimimetics and total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X, for the third and fourth quarters of calendar year 2018 and for the full calendar year 2019.

(ii) The weighted average ASP based on the most recent determinations by CMS.

(2) CMS uses the following methodology to calculate the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate:

(i) Determines utilization of oral and injectable calcimimetics by aggregating the total units of oral and injectable calcimimetics in paragraph (f)(1) of this section.

(ii) Determines a price for each form of the drug by calculating 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for the oral and injectable calcimimetic.

(iii) Calculates the total calcimimetic expenditure amount by multiplying the utilization of the oral and injectable calcimimetics determined in paragraph (f)(2)(i) of this section by their respective prices determined in paragraph (f)(2)(ii) of this section and adding the expenditure amount for both forms.

(iv) Calculates the average per treatment payment amount by dividing the total calcimimetic expenditure amount determined in paragraph (f)(2)(iii) of this section by the total number of paid hemodialysis-equivalent dialysis treatments in the third and fourth quarter of calendar year 2018 and the full calendar year 2019.

(v) Calculates the amount added to the ESRD PPS base rate by reducing the average per treatment payment amount determined in paragraph (f)(2)(iv) of this section by 1 percent to account for the outlier policy under § 413.237.

■ 4. Section 413.236 is amended by—

■ a. Revising paragraphs (a), (b) introductory text, (b)(2), (4) through (6), (c), (d) introductory text, and (d)(2); and

■ b. Adding paragraph (f).

The revisions and addition read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

(a) *Basis and definitions.* (1) Effective January 1, 2020, this section establishes an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(2) For purposes of this section, the following definitions apply:

Capital-related asset. Asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets.

Depreciation. The amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation.

Home dialysis machines. Hemodialysis machines and peritoneal dialysis cyclers in their entirety (meaning that one new part of a machine does not make the entire capital-related asset new) that receive FDA marketing authorization for home use and when used in the home for a single patient.

Particular calendar year. The year in which the payment adjustment specified in paragraph (d) of this section would take effect.

Straight-line depreciation method. A method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life.

Useful life. The estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

(b) *Eligibility criteria.* CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) to an ESRD facility for furnishing a covered equipment or supply only if the item:

* * * * *

(2) Is new, meaning within 3 years beginning on the date of the Food and Drug Administration (FDA) marketing authorization;

* * * * *

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

(5) Is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter; and

(6) Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications.* CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in paragraph (b) of this section and announce the results in the **Federal Register** as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year.

(d) *Transitional add-on payment adjustment for new and innovative equipment and supplies.* A new and innovative renal dialysis equipment or supply will be paid for using a transitional add-on payment adjustment for new and innovative equipment and supplies based on 65 percent of the MAC-determined price, as specified in paragraph (e) of this section. For capital-related assets that are home dialysis machines, payment is based on 65 percent of the pre-adjusted per treatment amount, as specified in paragraph (f)(1)(ii) of this section.

* * * * *

(2) Following payment of the transitional add-on payment adjustment for new and innovative equipment and supplies, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

* * * * *

(f) *Pricing of new and innovative renal dialysis equipment and supplies that are capital-related assets that are home dialysis machines.* (1) The MACs calculate a pre-adjusted per treatment amount, using the prices they establish under paragraph (e) of this section for a capital-related asset that is a home dialysis machine, as defined in paragraph (a)(2) of this section, as follows:

(i) Calculate an annual allowance to determine the amount that represents the portion of the cost allocable to 1 year, using the straight-line depreciation method, by dividing the MAC-determined price by its useful life of 5 years.

(ii) Calculate a per treatment amount for use in calculating the pre-adjusted per treatment amount by dividing the annual allowance, as determined in paragraph (f)(1)(i) of this section, by the expected number of treatments.

(iii) Calculate a pre-adjusted per treatment amount to determine the amount that is adjusted by the 65 percent under paragraph (d) of this section, by subtracting the average per treatment offset amount (as determined using the data sources and methodology specified in paragraphs (f)(2) and (3) of this section, respectively, of this section) from the per treatment amount (as determined in paragraph (f)(1)(ii) of this section) to account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own.

(2) The methodology specified in paragraph (f)(3) of this section for determining the average per treatment offset amount uses the following data sources:

(i) Dialysis machine and equipment cost, total cost across all dialysis modalities, the number of hemodialysis-equivalent home dialysis treatment counts, and the number of hemodialysis-equivalent total treatment

counts are obtained from renal facility cost reports (CMS form 265–11) and hospital cost reports (CMS form 2552–10) using calendar years 2017–2019 cost reports.

(A) Dialysis machine and equipment costs are obtained by summing lines 8.01 through 17.02 from Worksheet B, Column 4 for renal facility cost reports, and by summing lines 2 through 11 from Worksheet I–2 for hospital cost reports.

(B) Total cost across all dialysis modalities are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 2 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I–4, Column 2 for the hospital cost reports.

(C) Hemodialysis-equivalent total treatment counts are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I–4, Column 1 for the hospital cost reports.

(D) Hemodialysis-equivalent home dialysis treatment counts are obtained by summing lines 14.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 7 through 10 from Worksheet I–4, Column 1 for the hospital cost reports. In both renal facility and hospital cost reports, home Continuous Ambulatory Peritoneal Dialysis and home Continuous Cyclic Peritoneal Dialysis are reported as patient weeks, so a conversion factor of 3 is applied to obtain hemodialysis-equivalent treatment counts.

(ii) [Reserved]

(3) CMS uses the following methodology to calculate the average per treatment offset amount for home dialysis machines that is subtracted from the per treatment amount as determined in paragraph (f)(1)(ii) of this section to determine the pre-adjusted per treatment amount specified in paragraph (f)(1)(iii) of this section:

(i) Calculates annualized values for calendar year 2018 at the ESRD facility level for the metrics specified in paragraph (f)(2)(i) of this section by dividing the numbers of days the cost report spanned to compute a per-day metric, then multiplying the resulting value by the number of days in 2018 the cost report covered to compute the metrics attributable to the period covered by the cost report in 2018. Next, for ESRD facilities with multiple cost reports covering 2018 the resulting metrics are aggregated. Finally, each ESRD facility's aggregated metrics are annualized to cover the full calendar year 2018. The annualization factor for an ESRD facility is the total number of days in 2018 divided by the total days in 2018 covered by the ESRD facility's cost report(s).

(ii) Calculates an estimated home dialysis machine and equipment cost for each ESRD facility by multiplying the annualized dialysis machine and equipment cost determined in paragraph (f)(3)(i) of this section by the ESRD facility's hemodialysis-equivalent home dialysis treatment percentage. The hemodialysis-equivalent home dialysis treatment percentage for each facility is calculated by dividing annualized hemodialysis-equivalent home treatment count determined in paragraph (f)(3)(i) of this section by annualized hemodialysis-equivalent treatment count across all modalities determined in paragraph (f)(3)(i) of this section.

(iii) Calculates an average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 by dividing the sum of the estimated home dialysis machine and equipment cost in paragraph (f)(3)(ii) of this section across all ESRD facilities by the sum of annualized hemodialysis-equivalent home treatment counts determined in paragraph (f)(3)(i) of this section across all facilities.

(iv) Calculates the amount subtracted from the pre-adjusted treatment amount determined in paragraph (f)(1)(iii) of this section by inflating the average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 determined in paragraph (f)(3)(iii) to calendar year 2021. The average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 is inflated to calendar year 2021 by multiplying this value by the payment rate update factor required under section 1881(b)(14)(F)(i) of the Social Security Act for calendar years 2019, 2020, and 2021. This value is then divided by a scaling factor to be converted to the ESRD PPS payment scale. The scaling factor is calculated by dividing the calendar year 2018 total cost per treatment inflated to calendar year 2021 by the average ESRD PPS payment per treatment projected for calendar year 2021.

(v) Effective January 1, 2022, CMS annually updates the amount determined in paragraph (f)(3)(iv) of this section by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor.

■ 5. Section 413.237 is amended—

■ a. In paragraphs (a)(1)(i) through (iii) by removing the semicolon at the end of the sentence and adding a period in its place;

■ b. In paragraph (a)(1)(iv) by removing ''; and'' and adding a period in its place; and

■ c. By revising paragraph (a)(1)(v).

The revision reads as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(v) Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236, after the payment period has ended.

* * * * *

Dated: October 28, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 28, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–24485 Filed 11–2–20; 4:15 pm]

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Part III

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Polyvinyl Chloride and Copolymers Production Reconsideration; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0037; FRL–10015–41–OAR]

RIN 2060–AR73

National Emission Standards for Hazardous Air Pollutants: Polyvinyl Chloride and Copolymers Production Reconsideration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reconsideration of final rule.

SUMMARY: On April 17, 2012, the U.S. Environmental Protection Agency (EPA) promulgated National Emission Standards for Hazardous Air Pollutants (NESHAP) for Polyvinyl Chloride and Copolymers (PVC) Production at major and area sources. Subsequently, the Administrator received and granted petitions for reconsideration of the emission limits in the 2012 final rules for process vents, process wastewater, and stripped resin for major and area sources. In response to the petitions and after gathering additional information from PVC companies, the EPA is proposing revisions to emission limits in the 2012 major source rule for process vents and process wastewater. Although the EPA is not proposing revisions to emission limits in the 2012 area source rule, the EPA is proposing other amendments that affect both rules, including technical corrections and clarifications related to the standards for stripped resin, storage vessels (including the use of vapor balancing), equipment leaks, and closed vent systems. The EPA is also proposing to clarify text and correct typographical errors, grammatical errors, and cross-reference errors in both rules. In addition, the EPA is proposing to remove the affirmative defense provisions. We estimate that, if finalized, these proposed amendments would result in hazardous air pollutants (HAP) emissions reductions of 34 tons per year (tpy) with an annualized cost of $0.39 million.

DATES: Comments must be received on or before January 8, 2021. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before December 9, 2020.

Public hearing. If anyone contacts us requesting a public hearing on or before November 16, 2020, we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2002–0037, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2002–0037 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2002–0037.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2002–0037, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier (by scheduled appointment only):* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Ms. Jennifer Caparoso, Sector Policies and Programs Division (E143–01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4063; fax number: (919) 541–0516; and email address: *caparoso.jennifer@epa.gov.*

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. Please note that the EPA is deviating from its typical approach because the President has declared a national emergency. Due to the current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, the EPA cannot hold in-person public meetings at this time.

If requested, the virtual hearing will be held on November 24, 2020. The hearing will convene at 9:00 a.m. Eastern Time (ET) and will conclude at 3:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are not additional speakers. The EPA will announce further details on the virtual public hearing website at *https://www.epa.gov/stationary-sources-air-pollution/polyvinyl-chloride-and-copolymers-production-national-emission-0.*

The EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to speak at the virtual hearing, please use the online registration form available at: *https://www.epa.gov/stationary-sources-air-pollution/polyvinyl-chloride-and-copolymers-production-national-emission-0* or contact Ms. Virginia Hunt at (919) 541–0832 or by email at *hunt.virginia@epa.gov.* The last day to pre-register to speak at the hearing will be November 23, 2020. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers in approximate order at *https://www.epa.gov/stationary-sources-air-pollution/polyvinyl-chloride-and-copolymers-production-national-emission-0.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearing to run either ahead of schedule or behind schedule.

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically by emailing it to *caparoso.jennifer@epa.gov.* The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will

not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/polyvinyl-chloride-and-copolymers-production-national-emission-0.* While the EPA expects the hearing to go forward as set forth above, if requested, please monitor our website or contact Ms. Virginia Hunt at 919–541–0832 or *hunt.virginia@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or a special accommodation such as audio description, please pre-register for the hearing with Virginia Hunt and describe your needs by November 16, 2020. The EPA may not be able to arrange accommodations without advance notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2002–0037. All documents in the docket are listed in *Regulations.gov*. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. Publicly available docket materials are available electronically in *Regulations.gov*.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2002–0037. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information that you consider to be CBI or other information whose disclosure is restricted by statue. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

The EPA is temporarily suspending its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* as there may be a delay in processing mail and faxes. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID–19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2002–0037. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CBI Confidential Business Information
CDC Centers for Disease Control and Prevention
CEMS continuous emission monitoring systems
CFR Code of Federal Regulations
EPA Environmental Protection Agency
ET Eastern Time
GACT generally achievable control technology
HAP hazardous air pollutant(s)
HON Hazardous Organic NESHAP
ICR Information Collection Request
LDAR leak detection and repair
MACT maximum achievable control technology
NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NRDC Natural Resources Defense Council
NTTAA National Technology Transfer and Advancement Act
OMB Office of Management and Budget
ppm parts per million
ppmvd parts per million by volume dry
ppmw parts per million by weight
PRA Paperwork Reduction Act

PRD pressure relief device
PVC polyvinyl chloride and copolymers
PVCPU PVC production process unit
RDL representative detection level
RFA Regulatory Flexibility Act
SSM startup, shutdown, and malfunction
TEQ toxic equivalency
THC total hydrocarbons
TOHAP total non-vinyl chloride organic HAP
tpy tons per year
UMRA Unfunded Mandates Reform Act
UPL upper prediction limit

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. What is the source of authority for the reconsideration action?
B. Does this action apply to me?
C. Where can I get a copy of this document and other related information?
II. Background
III. Reconsideration Issues, Request for Public Comments, and Other Proposed Changes
A. Process Vents
B. Process Wastewater
C. Stripped Resin
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A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
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H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51
K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. What is the source of authority for the reconsideration action?

The statutory authority for this action is provided by sections 112 and 307(d)(7)(B) of the Clean Air Act (CAA) (42 U.S.C. 7412 and 7607(d)(7)(B)).

B. Does this action apply to me?

Regulated Entities. Categories and entities potentially regulated by this action are shown in Table 1 of this preamble.

TABLE 1—INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSED ACTION

NESHAP and source category	NAICS [1] code
Polyvinyl Chloride and Copolymers Production	325211

[1] North American Industry Classification System.

Table 1 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action for the source categories listed. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of these NESHAP, please contact the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/polyvinyl-chloride-and-copolymers-production-national-emission-0.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal at this same website.

A redline version of the regulatory language that incorporates the proposed changes in this action and supporting technical documents are available in the docket for this rulemaking.

II. Background

On July 10, 2002, the EPA promulgated the NESHAP for new and existing PVC production facilities located at major sources in 40 CFR part 63, subpart J (67 FR 45886). In that rulemaking, the EPA regulated vinyl chloride as a surrogate for all HAP emitted from PVC production and determined that the existing Vinyl Chloride NESHAP (40 CFR part 61, subpart F) reflected the application of maximum achievable control technology (MACT), thereby satisfying CAA section 112(d), except for equipment leaks at new sources. For equipment leaks, the EPA required that new sources comply with 40 CFR part 63, subpart UU.

In October 2003, Mossville Environmental Action Now and Sierra Club argued in the United States Court of Appeals for the District of Columbia Circuit (the court) that the EPA had failed to set emission standards for all HAP emitted by PVC plants. See *Mossville Environmental Action Now* v. *EPA,* 370 F.3d at 1232 (D.C. Cir. 2004). The EPA argued that it set emission standards for vinyl chloride as a surrogate for all HAP emitted from the source category because it was the predominant HAP used and emitted at PVC plants; however, the court ruled that the EPA did not adequately explain the basis for its decision to use vinyl chloride as a surrogate for the HAP other than vinyl chloride. The court ''vacated and remanded [the rule in its entirety] to the Agency for it to reconsider or properly explain its methodology for regulating [HAP] emitted in PVC production other than vinyl chloride by use of a surrogate.'' *Id.* at 370 F.3d at 1243.

On January 23, 2007 (72 FR 2930), the EPA promulgated the NESHAP for new and existing PVC production area sources in 40 CFR part 63, subpart DDDDDD, based on generally achievable control technology (GACT) under CAA section 112(d)(5), and required area sources to meet the requirements in the existing Vinyl Chloride NESHAP (40 CFR part 61, subpart F).

On April 17, 2012 (77 FR 22848), in response to the 2004 court remand in *Mossville Environmental Action Now,* the EPA finalized the NESHAP for PVC production at major sources under CAA sections 112(d)(2) and (3). In the same rulemaking, the EPA revised the area source standards under CAA section 112(d)(6). The April 17, 2012, final major and area source rules (herein referred to as the ''2012 final major and area source rules'') established emission limits and work practice standards for total organic HAP, and also for three specific HAP: Vinyl chloride, chlorinated dibenzodioxins and furans (dioxins and furans), and hydrogen chloride (HCl).[1] To determine the

[1] The EPA did not set emission limits or work practice standards for HCl from PVC area sources. Under CAA sections 112(c)(6) and 112(k), HCl was not determined to be one of the top 30 urban air toxics that pose the greatest potential health threat in urban areas; thus, regulation as an area source is not warranted. For additional details, see *https://www3.epa.gov/airtoxics/area/arearules.html.*

emissions limits and work practice standards, the EPA gathered information on PVC production through public comment, review of previously collected information, current literature, data from the National Emissions Inventory, meetings and voluntary information submissions by industry and the industry trade association. Also, in the form of an electronic survey and emission testing of HAP, the EPA collected information from PVC production facilities, as well as co-located ethylene dichloride and vinyl chloride facilities. All Agency correspondence related to the data gathering activities is provided in the docket for this rulemaking.

In June 2012, the EPA received four petitions for reconsideration on the 2012 final major and area source rules pursuant to CAA section 307(d)(7)(B) from the following petitioners: One petition from environmental groups (*i.e.,* Mossville Environmental Action Now, Louisiana Environmental Action Network, Air Alliance Houston, and Sierra Club); and three petitions from the regulated industry and their representatives (*i.e.,* PolyOne Corporation, Saint-Gobain Corporation and CertainTeed Corporation, and Vinyl Institute, Inc.). Copies of the petitions are provided in the docket for this rulemaking (see Docket Item Nos. EPA–HQ–OAR–2002–0037–0544, EPA–HQ–OAR–2002–0037–0568, EPA–HQ–OAR–2002–0037–0217, and EPA–HQ–OAR–2002–0037–0569). At the same time, the above petitioners, along with OxyVinyls, LP, petitioned the court for judicial review of the 2012 final major and area source rules. The petitioners primarily requested the EPA reconsider the emission limits for process vents, process wastewater, and stripped resin because they argued that it was not feasible to comment on the new data on which the EPA based the final emission limits. Petitioners also argued that they were not afforded the opportunity to comment on the subcategorization of process vents and stripped resin. Petitioners requested that the EPA reconsider and/or make changes to several other portions of the 2012 final major and area source rules; including requests that the EPA: (1) Set the emission limits using data that represents the entire industry; (2) allow vapor balancing as a method to control emissions from storage vessels; (3) allow leak detection and repair (LDAR) of pressure vessels; (4) revise emission profile requirements; (5) remove the requirement to install electronic indicators on each pressure relief device (PRD) that would be able to identify and record the time and duration of each pressure release; and (6) remove certain aspects of the bypass monitoring requirements, and leak monitoring and inspection requirements. In addition, one petitioner said the EPA's assumption that emission levels vary to the full extent of the 99th percent upper prediction limit (UPL) is wrong and unsupported by the record; and the EPA's decision to set MACT floors at 3 times the representative detection level (RDL) when 3 times the RDL is greater than the UPL is unlawful.

On September 28, 2012, the EPA sent letters to petitioners (see Docket Item Nos. EPA–HQ–OAR–2002–0037–0563 through EPA–HQ–OAR–2002–0037–0566) informing them that: (1) The EPA was granting reconsideration on at least petitioners' claims of inadequate opportunity to comment on the emission limits for process vents, process wastewater, and stripped resin for major and area sources; (2) the EPA intended to issue a **Federal Register** document initiating notice and comment rulemaking on the issues for which the Agency granted reconsideration; and (3) the EPA was continuing to review the other issues in the petitions for reconsideration and intended to take final action on all issues no later than the date on which the EPA takes final action on the reconsidered issues.

In 2014, Mexichem Specialty Resins, Inc., Vinyl Institute, Inc., Saint-Gobain Corporation and CertainTeed Corporation, and OxyVinyls, LP (Industry petitioners) petitioned the court to remove their case from abeyance.[2] The court removed the industry petitioners' cases from abeyance and, on May 29, 2015, the court rejected the Industry petitioners' arguments and denied their petitions for review. *Mexichem Specialty Resins, Inc.* v. *EPA,* 787 F.3d 544 (D.C. Cir. 2015). Based on this court decision, we consider all of the Industry petitioners' reconsideration requests related to the interaction between non-PVC and PVC-combined process vent limits and their subcategorization, vent gas absorbers, PRDs, and bypasses to be resolved, as those issues were addressed by the court.

Furthermore, on August 20, 2013, the court issued its decision in *National Association of Clean Water Agencies* v. *EPA,* which involved challenges to the EPA's MACT standards for Sewage Sludge Incineration, issued under CAA section 129. See 734 F.3d 1115. In this decision, the court remanded certain aspects of the rule for further explanation, including the question of how the UPL represents the MACT floor for new and existing units, as required by the CAA. The Sewage Sludge Incineration rule was issued on the same day as the Boilers and Commercial and Industrial Solid Waste Incineration rules, and used the same general methodology for calculating the MACT floors. For this reason, the EPA requested an opportunity to supplement the record in pending challenges to the Boilers and Commercial and Industrial Solid Waste Incineration rules, to provide the explanation of the Agency's analysis of variability in setting the MACT floor standards that the court believed was needed in the record for the Sewage Sludge Incineration rule. The court granted the EPA's motion for a remand of the record on May 15, 2014. Details of how the UPL is used to calculate the average emissions limitation achieved over time by the best performing source or sources is documented in the memorandum, *Use of the Upper Prediction Limit for Calculating MACT Floors,* which is available in the docket for this rulemaking. We also note that on July 29, 2016, the court determined our UPL approach is reasonable in *U.S. Sugar Corp* v. *EPA,* 830 F.3d 579, 639. Based on these details, we consider all of the petitioners' requests related to the EPA's methodology used to set MACT floors to be resolved.

We considered all other reconsideration petition requests and consolidated and grouped the issues for which we are granting reconsideration into distinct topics which are discussed in section III of this preamble.

III. Reconsideration Issues, Request for Public Comments, and Other Proposed Changes

To address selected issues raised in the four petitions for reconsideration and not resolved by the May 29, 2015, court decision (787 F.3d 544) as described above, the EPA is proposing revisions to the emission limits in the 2012 major source rule for process vents and process wastewater. In addition, the EPA is proposing other amendments to the 2012 final major and area source rules, including technical corrections and clarifications related to the standards for stripped resin, storage vessels (including the use of vapor balancing), equipment leaks, and closed vent systems. The EPA is also proposing to clarify text and correct typographical errors, grammatical errors, and cross-

[2] The petition for judicial review filed on behalf of Air Alliance Houston, Louisiana Environmental Action Network, Mossville Environmental Action Now, and Sierra Club, was severed from the industry case and is in abeyance pending the EPA's action on reconsideration.

reference errors in both rules. In addition, the EPA is proposing to remove the affirmative defense provisions. To ensure public participation in its final decisions, the EPA is requesting public comment on only these specific issues as described below. The EPA will not respond to any comments addressing any other provisions of the 2012 final major and area source rules or any other rules or issues.

A. Process Vents

Following the 2011 proposal (76 FR 29528), the EPA received comments and additional emissions data about process vents, and we used this information to revise the process vent MACT floors and impacts for the 2012 final major source rule. Details regarding the post-proposal data submittals are discussed in the memorandum, *Updated Information Collection and Additional Data Received for the Polyvinyl Chloride and Copolymers (PVC) Production Source Category,* which is available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2002–0037–0197). In the 2012 final major and area source rules, we established process vent emission limits for vinyl chloride, dioxins and furans, and total hydrocarbons (THC) or total organic HAP. For the 2012 final major source rule, we also established process vent emission limits for HCl as a surrogate for all acid gas HAP and chlorine gas. For the 2012 final area source rule, the process vent emission limits are based on the baseline level of control (*i.e.,* the control level that area sources were meeting for existing and new sources) and the testing and monitoring requirements are the same as the 2012 final major source rule. To ensure that batch process vent streams are tested at worst-case conditions, in the 2012 final major and area source rules, we required that each batch process vent stream be characterized under worst-case conditions by developing an emission profile. Also, in the 2012 final major and area source rules, we clarified the definitions for process vent, continuous process vent, and batch process vent and added a definition for miscellaneous vent. Refer to the preamble of the 2012 final major and area source rules (see section III of the 2012 final preamble, 77 FR 22850) for additional details about the process vent standards.

Petitioners primarily argue that it was not feasible to comment on the new data on which the EPA based the final process vent emission limits and subcategories; and as previously mentioned in section II of this preamble, on September 28, 2012, the EPA granted reconsideration on the process vent emission limits. We request public comments on the process vent emission limits and subcategories. However, as discussed later in this section of the preamble, we are also proposing to make changes to the process vent emission limits and subcategories; therefore, we also request public comments on these changes. In addition, a petitioner said the EPA did not provide opportunity to comment on the new, broader requirements for emission profiles that we added to the 2012 final major and area source rules. The petitioner also said the EPA did not provide opportunity to comment on the changes we made in the 2012 final major and area source rules to the definitions of process vent, continuous process vent, and batch process vent or the new definition for miscellaneous vent. The EPA is granting reconsideration on these other issues. Although we are not making any changes to the requirements in the 2012 final major and area source rules for emission profiles or to the definitions of process vent, continuous process vent, batch process vent, and miscellaneous vent, we request public comments on these requirements and definitions for the reasons set forth in the 2012 final rules (see sections III.D.1 and V.I of the 2012 final preamble, 77 FR 22855 and 22890).

In response to the petitioner's claims, the EPA issued a CAA section 114 Information Collection Request (ICR) on May 15, 2014, to PVC production companies to gather data to inform the reconsideration and potential revision of the process vent emission limits in the 2012 final major and area source rules (see Docket Item Nos. EPA–OAR–2002–0037–0600, EPA–OAR–2002–0037–0601, EPA–OAR–2002–0037–0602, EPA–OAR–2002–0037–0603, EPA–OAR–2002–0037–0604, EPA–OAR–2002–0037–0605, EPA–OAR–2002–0037–0622, and EPA–OAR–2002–0037–0623). The data collected are discussed in the memorandum, *Technical Analysis and Documentation to Support EPA's Reconsideration of 40 CFR part 63 Subpart HHHHHHH National Emission Standards for the Polyvinyl Chloride and Copolymers (PVC) Production Source Category,* which is available in the docket for this rulemaking. After reviewing all of the additional process vent data that we collected since the promulgation of the 2012 final major and area source rules, we are proposing changes to those rules.

First, we are proposing changes to the 2012 final major and area source rules related to the two subcategories for process vents (*i.e.,* the ''PVC-only process vent'' and ''PVC-combined process vent'' subcategories). Although we are not proposing to change our justification for establishing these two subcategories for process vents (see section III.B of the 2012 final preamble, 77 FR 22850), we are proposing to rename the ''PVC-only process vent'' subcategory the ''PVC process vent'' subcategory and revise the definition at 40 CFR 63.12005 such that a ''PVC process vent'' means a process vent that originates from a PVC production process unit (PVCPU) and is not combined with one or more process vents originating from the production of vinyl chloride monomer or ethylene dichloride prior to being controlled or emitted to the atmosphere. We are also proposing to revise the definition of ''PVC-combined process vent'' at 40 CFR 63.12005 such that a ''PVC-combined process vent'' means a process vent that originates from a PVCPU and is combined with one or more process vents originating from the production of vinyl chloride monomer or ethylene dichloride prior to being controlled or emitted to the atmosphere. In other words, instead of a vent which is combined with one or more process vents originating from any other source category (as is the case in the 2012 final major and area source rules), we are narrowing the definition of a ''PVC-combined process vent'' to refer to a vent that is combined with one or more process vents originating from the production of vinyl chloride monomer or ethylene dichloride.[3] [4] These proposed definition changes more accurately reflect the additional process vent data that we collected since the promulgation of the 2012 final major and area source rules, given that owners and operators of some vinyl chloride monomer or ethylene dichloride production units combine their vinyl chloride monomer, ethylene dichloride, and PVC process vents into one stream prior to control and these combined streams have higher chlorinated loads and flow rates than a PVC process vent (as defined in this proposal). These proposed definition changes will impact

[3] We are also including a sentence in each of these definitions to clarify that vent streams from process components associated with the stripped resin downstream of the resin stripper (*e.g.,* dryers, centrifuges, filters) are not considered a PVC process vent or a PVC-combined process vent because these vent streams are subject to the stripped resin standards (see section III.C of this preamble).

[4] We note that although these proposed changes are being made directly in the 2012 final major source rule, these proposed changes also result in revisions to the 2012 final area source rule because 40 CFR 63.11144(b) references 40 CFR 63.12005.

the subcategory designations of two PVC facilities if finalized as proposed. Both facilities currently are in the ''PVC-combined process vent'' subcategory and with the proposed definition changes, the facilities would be in the ''PVC process vent'' subcategory. The impacts to the emission limits for each of the proposed subcategories due to the proposed definition changes are discussed below.

Second, in light of the court's decision in *Mexichem Specialty Resins, Inc.* v. *EPA,* 787 F.3d 544 (D.C. Cir. 2015), we are clarifying at 40 CFR 63.11925(a) that if an applicable process vent stream at a PVCPU is comingled with a vent stream from one or more non-PVCPU sources (*e.g.,* a vent stream from a vinyl chloride monomer, ethylene dichloride production, or other chemical manufacturing process unit subject to the Hazardous Organic NESHAP (HON), 40 CFR part 63, subparts G, F, and H), and the comingled streams are vented through a shared control device, then each emission standard (and subsequent control device monitoring, recordkeeping, reporting, and other requirements) from both the PVC NESHAP and any other NESHAP to which the comingled vent stream is subject applies. In *Mexichem Specialty Resins, Inc.* v. *EPA,* the court ruled that if ''a PVC manufacturer chooses to discharge combined emissions from PVC and non-PVC processes through a single vent, that manufacturer must comply with limits applicable to both and, where they differ, comply with the more stringent of the two.'' For this reason, and to clarify what the rules are intended to regulate, we are also proposing to revise 40 CFR 63.11140(c) by removing the last sentence and 40 CFR 63.11865 by removing the phrase ''or to chemical manufacturing process units, as defined in § 63.101, that produce vinyl chloride monomer or other raw materials used in the production of polyvinyl chloride and copolymers'' and we are proposing at 40 CFR 63.12005 to remove the last sentence in the definition of PVCPU. We note that although the proposed changes at 40 CFR 63.11925(a) and 40 CFR 63.12005 are being made directly in the 2012 final major source rule, these proposed changes also result in revision to the 2012 final area source rule because 40 CFR 63.11142(f)(8) references 40 CFR 63.11925 and 40 CFR 63.11144 references 40 CFR 63.12005.

Third, given that we are proposing to revise the definitions of ''PVC process vent'' and ''PVC-combined process vent'' as discussed above (and which are referenced in the area source rule), we are also proposing to amend the emission limits for PVC-combined process vents in the 2012 final area source rule by eliminating the PVC-combined process vent limits in the area source rule and instead require ''PVC-combined process vents'' at area sources to meet the major source process vent emission limits for ''PVC-combined process vents.'' Based on the additional process vent data that we collected since the promulgation of the 2012 final major and area source rules, we determined that any facility producing vinyl chloride monomer and/or ethylene dichloride is a major source (as defined in CAA section 112(a)) subject to the HON. Therefore, taking into consideration our proposed definition of ''PVC-combined process vent,'' we do not believe that there is any scenario where a PVC production area source can combine its process vents with one or more process vents originating from the production of vinyl chloride monomer or ethylene dichloride and that combined process vent be routed to a control device being used to comply with only an area source NESHAP. We estimate that there would be no impact on any facility for making this change (*i.e.,* to eliminate the emission limits for PVC-combined process vents in the 2012 final area source rule and instead require ''PVC-combined process vents'' at an area source meet the major source process vent emission limits). We are proposing at 40 CFR 63.11141(f) that all affected area sources that commenced construction or reconstruction on or before May 20, 2011, must be in compliance with this change within 3 years after the date of publication of the final rule in the **Federal Register**. We also are proposing at 40 CFR 63.11141(f) that all affected area sources that commenced construction or reconstruction after May 20, 2011, must be in compliance with this change upon the date of publication of the final rule in the **Federal Register** or initial startup, whichever is later. We are not aware of any sources that have commenced construction or reconstruction after May 20, 2011, which would be impacted by the application of the changes.

Fourth, we are proposing to revise the process vent emission limits in the 2012 final major source rule. As part of the May 15, 2014, CAA section 114 ICR, we asked for sampling and analysis of HAP including vinyl chloride, HCl, dioxins/furans, and THC from process vents operating at maximum mass loading of all HAP compounds under normal operation at eight PVC production facilities. Those data were incorporated with the previously submitted data used to support the 2012 final major source rule process vent emission limits. We then recalculated the process vent emission limits for vinyl chloride, total organic HAP, HCl, dioxins/furans, and THC accounting for the additional data received in response to the May 15, 2014, CAA section 114 ICR and also accounting for the change in subcategory for two PVC facilities based on our proposed revisions to the process vent subcategory definitions. To account for variability, we calculated the proposed MACT floors for vinyl chloride, total organic HAP, HCl, and dioxins/furans for existing and new sources using a 99-percent UPL calculation. Given the large amount of data obtained, we calculated the proposed MACT floors for THC for existing and new sources using a 99-percent upper limit calculation. Tables 2 and 3 of this preamble compare the 2012 final major source rule PVC process vent emission limits and PVC-combined process vent emission limits, respectively, to the process vent emission limits that we are proposing in this action. Also, as part of a beyond-the-floor analysis, we analyzed the cost and emissions reductions for an existing facility to install a refrigerated condenser prior to the existing thermal oxidizer and acid gas scrubber to meet the proposed new source standards for process vents; and we determined that the overall annual cost would be $7.2 million, and the annual emissions reductions would be 105 tons of HAP per year (approximately $68,000/ton cost effectiveness). Furthermore, the only beyond-the-floor option we identified for new sources is a refrigerated condenser prior to the thermal oxidizer and acid gas scrubber. However, similar to the analysis for existing sources, installing a refrigerated condenser prior to the thermal oxidizer and acid gas scrubber at a new source to achieve beyond-the-MACT-floor level of control would also not be cost effective (*i.e.,* higher cost with potentially less HAP removal than existing sources). We did not identify any other measures or control technologies to further reduce emissions from process vents in the PVC production industry. Based on this analysis, we are proposing that it is not cost effective to go beyond-the-floor for process vents at existing or new sources. Our emission limit calculations, beyond-the-floor analysis, and the methodology we used to calculate costs and emission reductions are discussed in the memorandum, *Technical Analysis and Documentation to Support EPA's Reconsideration of 40 CFR part*

63 Subpart HHHHHHH National Emission Standards for the Polyvinyl Chloride and Copolymers (PVC) Production Source Category, which is available in the docket for this rulemaking.

TABLE 2—COMPARISON OF 2012 FINAL MAJOR SOURCE EMISSION LIMITS AND PROPOSED EMISSION LIMITS FOR PVC PROCESS VENTS

Pollutant	2012 Final major rule emission limits for pvc process vents		Proposed emission limits for pvc process vents	
	Existing sources	New sources	Existing sources	New sources
Vinyl Chloride [1]	6.0	0.56	0.85	0.85
Total Organic HAP [1]	56	5.5	22	1.3
HCl [1]	78	0.17	0.64	0.17
Dioxins/Furans [2]	0.038	0.038	0.035	0.035
THC [3]	9.7	7.0	5.1	2.2

[1] Parts per million by volume dry (ppmvd) @3-percent (%) oxygen (O_2).
[2] Nanograms per dry standard cubic meters (ng/dscm) @3% O_2 toxic equivalency (TEQ).
[3] ppmvd as propane @3% O_2.

TABLE 3—COMPARISON OF 2012 FINAL MAJOR SOURCE EMISSION LIMITS AND PROPOSED EMISSION LIMITS FOR PVC-COMBINED PROCESS VENTS

Pollutant	2012 final major rule emission limits for PVC-combined process vents		Proposed emission limits for PVC-combined process vents	
	Existing sources	New sources	Existing sources	New sources
Vinyl Chloride [1]	1.1	0.56	0.85	0.85
Total Organic HAP [1]	9.8	5.5	9.7	5.9
HCl [1]	380	1.4	3.9	1.4
Dioxins/Furans [2]	0.051	0.034	0.68	0.051
THC [3]	4.2	2.3	9.1	2.2

[1] ppmvd @3% O_2.
[2] ng/dscm @3% O_2 TEQ.
[3] ppmvd as propane @3% O_2.

We are proposing the revised major source process vent emission limits in new Tables 1b and 2b to 40 CFR part 63, subpart HHHHHHH; and we are proposing that all affected major sources that commenced construction or reconstruction on or before May 20, 2011, must be in compliance with these changes within 3 years after the date of publication of the final rule in the **Federal Register**. We also are proposing that all affected major sources that commenced construction or reconstruction after May 20, 2011, must be in compliance with these changes upon the date of publication of the final rule in the **Federal Register** or initial startup, whichever is later. We are not aware of any major sources that have commenced construction or reconstruction after May 20, 2011, which would be impacted by the application of the changes. See proposed 40 CFR 63.11875(e). Also, at any time before these compliance dates, we are proposing at 40 CFR 63.11880(d) that an affected major source may choose to comply with the revised emission limits in Tables 1b and 2b to 40 CFR part 63, subpart HHHHHHH, in lieu of the emission limits in Tables 1 and 2 to 40 CFR part 63, subpart HHHHHHH. Also, as previously mentioned in section II of this preamble, on September 28, 2012, the EPA granted reconsideration on the emission limits. We are not making any changes to the process vent emission limits in the area source rule; however, we request public comments on these emission limits.

Finally, we are proposing to revise several paragraphs throughout the 2012 final major and area source rules, (including process vent related requirements in 40 CFR 63.11925 through 63.11950) to properly reference the proposed Tables 1b and 2b to 40 CFR part 63, subpart HHHHHHH. For example, for 40 CFR part 63, subpart DDDDDD, although 40 CFR 63.11925 is referenced in 40 CFR 63.11142(f)(8), we are proposing to revise the introduction paragraph at 40 CFR 63.11142(f) to ensure that whenever reference is made to Tables 1, 1b, 2, or 2b to 40 CFR part 63, subpart HHHHHHH, we mean Table 1 or 2 to 40 CFR part 63, subpart DDDDDD, for purposes of compliance with the 2012 area source process vent standards. We are also proposing several other editorial corrections and clarifications to the process vent requirements in 40 CFR 63.11925 through 63.11950. These proposed amendments are discussed in section III.I of this preamble.

The EPA is soliciting comment on all of the proposed changes discussed in this section of the preamble (*i.e.,* the revised subcategories for process vents, the clarifications to 40 CFR 63.11140(c), 63.11865, 63.11925(a), and 63.12005 addressing comingled vent streams, the elimination of the emission limits for PVC-combined process vents in the 2012 final area source rule, the revised major source process vent emission limits, the compliance dates, and whether there are any sources that commenced construction after May 20, 2011). Except for the proposed major source process vent emission limits, we note (as previously mentioned) that all of the other proposed changes discussed in this section of the preamble are also being proposed for the 2012 area source rule at 40 CFR 63.11142(f)(8) through (13) and 63.11144 because 40 CFR 63.11925 through 63.11950 and 63.12005 are referenced in those

requirements. If it is determined that there are sources that have commenced construction or reconstruction after May 20, 2011, then we will need to add additional requirements.

B. Process Wastewater

The 2012 final major source rule contains vinyl chloride and total non-vinyl chloride organic HAP (TOHAP) emission limits for process wastewater. For the 2012 final major source rule, the vinyl chloride emission limits were calculated based on one year of sampling data provided post-proposal by the industry. The major source TOHAP emission limits were based on information and data provided by industry in response to the August 21, 2009, CAA section 114 ICR, corrections to those data provided by the PVC industry during the public comment period, and supplemental wastewater sampling data provided during the public comment period by one PVC manufacturer. The August 21, 2009, CAA section 114 ICR is documented in the memoranda, *Information Collection for the Polyvinyl Chloride and Copolymers (PVC) Production Source Category* and *Updated Information Collection* and *Additional Data Received for the Polyvinyl Chloride and Copolymers (PVC) Production Source Category,* which are available in the docket for this rulemaking (see Docket Item Nos. EPA–HQ–OAR–2002–0037–0099 and EPA–HQ–OAR–2002–0037–0197, respectively). Refer to the preamble of the 2012 final major and area source rules (see section III of the 2012 final preamble, 77 FR 22850) for additional details about the emission limits for process wastewater.[5]

Petitioners primarily argue that it was not feasible to comment on the new data on which the EPA based the final process wastewater emission limits; and as previously mentioned in section II of this preamble, on September 28, 2012, the EPA granted reconsideration on this issue. The petitioners argued that the EPA did not base the TOHAP emission limits on emission levels actually achieved by the best performing sources in the source category. One of the petitioners said that the EPA did not provide rationale for why nine out of 18 facilities (for which it had data) represented the top performing sources. Other petitioners argued that the data points do not reflect actual samples of PVC facility process wastewater taken during actual operations.

In response to the petitioner's claims, the EPA issued a CAA section 114 ICR on November 8, 2012, to PVC production companies to gather data to inform the reconsideration and potential revision of the process wastewater emission limits in the 2012 final major and area source rules. Also, the EPA issued an additional CAA section 114 ICR on April 1, 2014, to two companies that were not included in the November 8, 2012, CAA section 114 request. These two CAA section 114 ICRs are available in the docket for this rulemaking (see Docket Item Nos. EPA–OAR–2002–0037–0543, EPA–OAR–2002–0037–0592, EPA–OAR–2002–0037–0593, and EPA–OAR–2002–0037–0594). The data collected are discussed in the memorandum, *Technical Analysis and Documentation to Support EPA's Reconsideration of 40 CFR part 63 Subpart HHHHHHH National Emission Standards for the Polyvinyl Chloride and Copolymers (PVC) Production Source Category,* which is available in the docket for this rulemaking. Each owner or operator was required to take one grab sample from each PVC process wastewater treatment stream for 30 consecutive days and then analyze the samples for specified HAP using the prescribed EPA test methods. If a facility had a batch PVC operation that did not operate 30 consecutive days, then it was required to collect samples at least once for each day while any batch wastewater treatment system was operating such that at least 30 samples were analyzed. Data were also collected on other wastewater streams (*i.e.,* streams not stripped and streams slated for on-site or off-site biological treatment units), including average flow rate characteristics, origination, and destination information. After reviewing all of the additional process wastewater data that we collected since the promulgation of the 2012 final major and area source rules, we are proposing changes to the 2012 final major and area source rules.

First, we are proposing to revise the process wastewater vinyl chloride emission limit for major sources. Under the proposed amendments, process wastewater streams at existing major sources would be required to meet an emission limit of 0.73 parts per million by weight (ppmw) for vinyl chloride (in lieu of the 6.8 ppmw vinyl chloride process wastewater emission limit in the 2012 major source rule for existing affected sources) before being exposed to the atmosphere or discharged from the affected source (see proposed Table 1b to 40 CFR part 63, subpart HHHHHHH). Process wastewater streams at new major sources would be required to meet an emission limit of 0.57 ppmw for vinyl chloride (in lieu of the 0.28 ppmw vinyl chloride process wastewater emission limit in the 2012 major source rule for new affected sources) before being exposed to the atmosphere or discharged from the affected source (see proposed Table 2b to 40 CFR part 63, subpart HHHHHHH). Given the large amount of data obtained, we calculated these MACT floors (*i.e.,* the proposed 0.73 ppmw and 0.57 ppmw vinyl chloride emission limits for existing and new major sources, respectively) using a 99-percent upper limit calculation. Also, we analyzed a beyond-the-floor option for controlling vinyl chloride from process wastewater at existing sources, specifically evaluating the cost and emissions reductions for an existing facility to meet the level of control that we are proposing for new sources, based on replacement of their existing wastewater steam stripper. We determined that the overall annual cost (including installation and operation) would be about $11 million, and the annual emissions reductions would be 1.3 tons of HAP per year (approximately $8.6 million/ton cost effectiveness). Furthermore, the only beyond-the-floor option we identified for new sources is a larger or secondary steam stripper. However, similar to the analysis for existing sources, installing a larger or secondary steam stripper at a new source to achieve beyond-the-MACT-floor level of control would also not be cost effective (*i.e.,* higher cost with potentially less HAP removal than existing sources). We did not identify any other measures or control technologies to further reduce emissions from process wastewater in the PVC production industry. Based on this analysis, we are proposing that it is not cost effective to go beyond-the-floor for process wastewater at existing or new sources. Our MACT floor emission limit calculations, beyond-the-floor analysis, and the methodology we used to calculate costs and emission reductions are discussed in the memorandum, *Technical Analysis and Documentation to Support EPA's Reconsideration of 40 CFR part 63 Subpart HHHHHHH National Emission Standards for the Polyvinyl Chloride and Copolymers (PVC) Production Source Category,* which is available in the docket for this rulemaking. Also, as previously

[5] We note that subsequent to the April 17, 2012, rulemaking, PVC industry stakeholders notified the EPA that the data used to set the new and existing area source TOHAP process wastewater emission limits were not based on data from the PVC Production source category. The EPA agreed with the PVC industry stakeholders and on February 4, 2015, the EPA issued a direct final rule (80 FR 5938, February 4, 2015) withdrawing the TOHAP process wastewater emission standards in 40 CFR part 63, subpart DDDDDD, for new and existing PVC production area sources.

mentioned in section II of this preamble, on September 28, 2012, the EPA granted reconsideration on the emission limits. We are not making any changes to the wastewater emission limits in the area source rule; however, we request public comments on these emission limits.

Second, we are proposing to remove the major source process wastewater TOHAP emission limit and establish vinyl chloride as a surrogate for TOHAP for major and area sources. As noted above, petitioners argue that the EPA did not base the TOHAP emission limits on emission levels actually achieved by the best performing sources in the source category. One of the petitioners said that the EPA did not set the MACT floor using data for the top performing sources. Another petitioner argued that the data points do not reflect actual samples of PVC facility process wastewater taken during actual operations. We are proposing to eliminate the process wastewater TOHAP emission limit and to be more fully responsive to the court's original request that the EPA ''properly explain its methodology for regulating [HAP] emitted in PVC production other than vinyl chloride by use of a surrogate.'' See *Mossville Environmental Action Now* v. *EPA,* 370 F.3d at 1232 (D.C. Cir. 2004). In this proposal, we have redetermined and are further explaining the basis for our conclusion that vinyl chloride is a suitable surrogate for establishing process wastewater emission limits for organic HAP. We note that the court (370 F.3d at 1242–43) held that the EPA has authority to use a surrogate ''if it is reasonable to do so[.]'' For the reasons discussed below, we have determined that vinyl chloride is a reasonable surrogate for TOHAP emitted from process wastewater at PVC production facilities.

Steam stripping is an effective wastewater treatment technology that has been used as the basis of wastewater emission control requirements in many rules, including the 40 CFR part 63 MACT for chemical process industries, such as the HON, Miscellaneous Organic Chemical Manufacturing NESHAP, and Polymers and Resins NESHAP as well as the 40 CFR part 61 Benzene Waste Operations NESHAP. The approach is based on the idea that removal of pollutants from wastewater prior to discharge into a facility's wastewater collection and treatment system will limit air emissions resulting from volatilization of these pollutants from downstream process drains and conveyances that are open to the atmosphere, as well as from the downstream biological treatment system, including biological treatment units that are agitated and aerated to supply the microorganisms with O_2. Conversely, those pollutants that are not effectively removed by a steam stripper will be even less likely to volatilize in collection and treatment and will be controlled in the facility's biological treatment system.

All PVC manufacturers have high concentrations of vinyl chloride in their process wastewater and steam stripping is widely used by PVC manufacturers to remove and recover vinyl chloride from process wastewater streams. The best performers that the MACT floor is based on are those strippers that have the lowest vinyl chloride concentrations in the bottoms (outlet) stream exiting the steam stripper; that is, the most effective strippers are those that result in the lowest concentration of vinyl chloride in the bottoms stream.

Based on the data we received in response to our CAA section 114 ICRs of PVC manufacturers, 33 non-vinyl chloride HAP are also present in the bottoms of the stripped wastewater streams. While many of these non-vinyl chloride HAP are removed using steam stripping, some are removed to a lesser degree. The EPA thoroughly examined the fundamentals of steam stripping wastewater (including calculating the HAP fraction removed (Fr) values [6] for a model steam stripper and the fraction emitted (Fe) values [7] for numerous HAP from wastewater) during the original rulemaking of the HON (see Legacy Docket A–90–23). Based on this information as well as the data we received in response to our CAA section 114 ICRs, we determined that 25 of the 33 non-vinyl chloride HAP in the stripped wastewater have lower concentrations than the average vinyl chloride concentration and have Fr values of 0.99 which is the same Fr value for vinyl chloride.[8] In other words, vinyl chloride and most non-vinyl chloride HAP are effectively removed from the wastewater stream using steam stripping. We, therefore, conclude that vinyl chloride is a reasonable surrogate for these HAP. Although the remaining eight non-vinyl chloride HAP have stripper bottoms concentrations higher than vinyl chloride and have Fr values from 0.31 (methanol) to 0.99 (vinyl acetate),[9] these HAP are not likely to be emitted to the atmosphere because these HAP have low Fe values, significantly less than that of vinyl chloride. The Fe values for these compounds range from 0 (ethylene glycol) to 0.59 (vinyl acetate), compared to vinyl chloride's Fe value of 0.97. As a result, these HAP other than vinyl chloride that remain in the stripped wastewater are more likely to remain in the wastewater collection system and will be readily biodegraded in the biological treatment unit. Furthermore, we observed that non-vinyl chloride HAP concentrations at the outlet of the steam stripper are the result of varied resin recipe slates in use throughout the industry, and, therefore, do not correlate with the effectiveness of the steam stripper at removing vinyl chloride. For example, resin grade recipes lower in hard-to-strip TOHAP could allow for poorer stripper performance if TOHAP were being relied to determine MACT. Therefore, the steam strippers that are the best performers can be identified by their low vinyl chloride concentrations and not by the non-vinyl chloride HAP concentrations in the stripper bottoms.

In summary, vinyl chloride serves as an appropriate surrogate for determining the MACT floor for process wastewater. First, vinyl chloride is the predominant HAP and is present in all process wastewater streams. Second, the best performing strippers are identified by low vinyl chloride concentrations in the stripper bottoms and are also the most effective strippers at removing non-vinyl chloride HAP. The other non-vinyl chloride HAP present in the stripper bottoms are a reflection of the resin recipe and not the effectiveness of the stripper. The non-vinyl chloride HAP that are in the stripper bottoms will not volatilize in collection systems

[6] The Fr is the mass fraction of a HAP that is stripped from the wastewater. The Fr values for individual HAP in a model steam stripper were estimated using Henry's Law Constants at 100 degrees Celsius during the development of the HON. See 57 FR 62641, December 31, 1992; 59 FR 19443 and 4, April 22, 1994; and the memoranda, *Henry's Law Constants for the 83 HAP's Regulated in the Proposed HON Wastewater Provisions;* and *Efficiency of Steam Stripper Trays to Treat Wastewater Streams: Prediction of the Fraction Removed (Fr) for Specific Compounds,* which are available in the docket for this rulemaking.

[7] The Fe is the mass fraction of a HAP that is emitted from the wastewater collection and downstream biological treatment system. The Fe values for individual HAP were calculated during the development of the HON. See 57 FR 62641, December 31, 1992; 59 FR 19443 and 4, April 22, 1994; and the memorandum, *Estimation of Air Emissions from Model Wastewater Collection and Treatment Plants Systems,* which is available in the docket for this rulemaking.

[8] See the memorandum, *Analysis of HAP in PVC Process Wastewater,* which is available in the docket for this rulemaking.

[9] Only three of 15 facilities reported data where vinyl acetate concentrations in the stripper bottoms were higher than vinyl chloride. One facility is no longer in operation and the other two are vinyl chloride/vinyl acetate copolymer producers. Therefore, the higher vinyl acetate fraction is likely the result of resin recipe influence rather than stripper performance since vinyl chloride and vinyl acetate have the same Fr value.

and be effectively treated in the biological treatment unit. The regulatory objective of this rule is to control air emissions of HAP from wastewater streams and not to control HAP that are in the wastewater streams. Focusing on vinyl chloride rather than total organic HAP for setting standards for PVC process wastewater not only ensures identification of the best performing wastewater strippers for the primary HAP emitted from the source category, but also ensures the effective control of air emissions of non-vinyl chloride organic HAP from wastewater.[10] Additional details about our proposed surrogacy are provided in the memorandum, *Analysis of HAP in PVC Process Wastewater,* which is available in the docket for this rulemaking.

We are proposing these changes (*i.e.,* to revise the process wastewater vinyl chloride emission limit and eliminate the process wastewater TOHAP emission limit) in new Tables 1b and 2b to 40 CFR part 63, subpart HHHHHHH; and we are proposing that all affected major sources that commenced construction or reconstruction on or before May 20, 2011, must be in compliance with these changes within 3 years after the date of publication of the final rule in the **Federal Register**. We also are proposing that all affected major sources that commenced construction or reconstruction after May 20, 2011, must be in compliance with these changes upon the date of publication of the final rule in the **Federal Register** or initial startup, whichever is later. See proposed 40 CFR 63.11875(e). We are not aware of any major sources that have commenced construction or reconstruction after May 20, 2011, which would be impacted by the application of the changes. Also, at any time before these compliance dates, we are proposing at 40 CFR 63.11880(d) that an affected major source may choose to comply with the revised emission limits in Tables 1b and 2b to 40 CFR part 63, subpart HHHHHHH, in lieu of the emission limits in Tables 1 and 2 to 40 CFR part 63, subpart HHHHHHH.

Finally, we are proposing to revise several paragraphs throughout the major source rule (including process wastewater related requirements in 40 CFR 63.11965 through 63.11985) to properly reference the proposed Tables 1b and 2b to 40 CFR part 63, subpart HHHHHHH, and to address the elimination of the major source process wastewater TOHAP emission limit; and we are proposing to clarify in 40 CFR 63.11965(e) that only 40 CFR 63.105(b) and (c) apply to maintenance wastewater containing HAP listed in Table 10 to 40 CFR part 63, subpart HHHHHHH. We are also proposing to correct a typographical error in Table 9 to 40 CFR part 63, subpart HHHHHHH, to be consistent with the requirement at 40 CFR 63.11980(a)(4)(i). Specifically, we are clarifying in Table 9 to 40 CFR part 63, subpart HHHHHHH, that compliance with the wastewater emission limit is based on the results from one grab or composite sample.

The EPA is soliciting comment on all of the proposed changes discussed in this section of the preamble (*i.e.,* the revised process wastewater vinyl chloride emission limits, the elimination of the process wastewater TOHAP emission limits, the compliance dates, whether there are any sources that commenced construction after May 20, 2011, the clarification to 40 CFR 63.11965(e), and the correction in Table 9 to 40 CFR part 63, subpart HHHHHHH). We note that the proposed clarification in 40 CFR 63.11965(e) is also being proposed for the 2012 area source rule at 40 CFR 63.11142(f)(17) because 40 CFR 63.11965 is referenced in those requirements; however, the proposed process wastewater vinyl chloride emission limits do not affect the 2012 area source rule at 40 CFR 63.11142(f)(17). Although 40 CFR 63.11965 through 63.11980 are referenced in 40 CFR 63.11142(f)(17), we are proposing to revise the introduction paragraph at 40 CFR 63.11142(f) to ensure that whenever reference is made to Tables 1, 1b, 2, or 2b to 40 CFR part 63, subpart HHHHHHH, we mean Table 1 or 2 to 40 CFR part 63, subpart DDDDDD, for purposes of compliance with the 2012 area source wastewater standards. If it is determined that there are major sources that have commenced construction or reconstruction after May 20, 2011, then we will need to add additional requirements.

C. Stripped Resin

1. Subcategories and Emission Limits

Petitioners maintain that it was not feasible to comment on the new data on which the EPA based the final stripped resin emission limits and subcategories; and as previously mentioned in section II of this preamble, on September 28, 2012, the EPA granted reconsideration on the emission limits. We are not making any changes to the stripped resin emission limits and subcategories in the 2012 final major and area source rules; however, we request public comments on these emission limits and subcategories.

2. Alternative Emission Limit Format for Compliance With Stripped Resin Standards

The existing Vinyl Chloride NESHAP (40 CFR part 61, subpart F) provides emissions standards for the sources following the stripper ''stated in two ways'' (40 FR 59541, December 24, 1975). One of these two formats for emissions standards is in ppmw of the stripped resin at the outlet of the stripper and is used in both 40 CFR part 61, subpart F, and the 2012 final major and area source rules, as seen in 40 CFR 61.64(e)(1), Tables 1 and 2 to 40 CFR part 63, subpart DDDDDD, and Tables 1 and 2 to 40 CFR part 63, subpart HHHHHHH. The second format is a mass emissions to the atmosphere, which is given as gram (g) HAP per kilogram (kg) of product resin on a dry basis from the stripper (also given in pound per ton format) and is only currently available in 40 CFR 61.64(e)(2). The EPA originally offered these two ''ways'' of presenting an equivalent emission limit to acknowledge that there were two distinctively different techniques to control these sources—add-on control devices or improved stripping, and that different measurement and enforcement methods are applicable to each technique (40 FR 59541).[11] At the time, we also acknowledged that stripping is the primary control technology on which the standards are based, lending credence for including the ppmw format resin standard in the 2012 final major and area source rules. However, we realize that some sources may find compliance flexibility in complying with a mass emissions limit instead of a stripped resin content, especially if centrifuges, blend tanks, and other process components downstream of the stripper are closed to the atmosphere, controlled with closed vent systems, and routed to a control device. Therefore, we have calculated mass emissions-formatted standards that are equivalent to the resin content standards of the 2012 final major and area source rules using the conversion methods used in the original 40 CFR part 61, subpart F standards (*i.e.,*

[10] See 57 FR 62641, December 31, 1992.

[11] The EPA noted that the two emission limits ''are equivalent if it is assumed that all residual vinyl chloride in the resin leaving a stripper is emitted into the atmosphere at the polyvinyl chloride plant.'' While acknowledging that a small proportion of vinyl chloride might be left in the resin when it leaves the plant, the residual vinyl chloride monomer left in the resin after stripping would be emitted into the atmosphere at some point, and, therefore, the EPA determined that the residual vinyl chloride monomer in resin limits serve as an emission limitation ''specified in a form which is compatible with the only practical method for determining compliance.''

converting the ppmw standard to g/kg, or part per thousand by weight for the equivalent mass emission rate), and we are proposing to include these alternative emission limits in Tables 1 and 2 to 40 CFR part 63, subpart DDDDDD, and Tables 1b and 2b to 40 CFR part 63, subpart HHHHHHH. In doing so in the same manner as the original 40 CFR part 61, subpart F standards, we are ensuring that the alternate emission limits can be implemented and enforced, will be clear to sources, and most importantly, will be equivalent to the level of control required by the MACT standards. We are proposing at 40 CFR 63.11960(b)(2) that if the affected source chooses to comply with the alternative mass emission rates, then the process components associated with the stripped resin downstream of the resin stripper (*e.g.,* dryers, centrifuges, filters) must be enclosed and routed through a closed vent system meeting the requirements in 40 CFR 63.11925 through 63.11950 for the closed vent system and control device. We are also proposing calculation procedures at 40 CFR 63.11960(g) and (h) that you must use if you elect to demonstrate initial or continuous compliance with the alternative mass emissions rates. In addition, we are proposing to clarify the reporting and recordkeeping at 40 CFR 63.11985(b)(7) and 40 CFR 63.11990(h)(3) to reflect the proposed option of complying with the alternative mass emissions rates. The monitoring requirements for sources using the alternative emission limits would include the same stack testing methods and procedures required for process vent performance testing instead of resin sampling and concentration analyses. By proposing these alternative emission limits, we are providing the same level of compliance flexibility afforded by the Vinyl Chloride NESHAP. Tables 4 and 5 of this preamble present the proposed mass emission limits for existing and new sources, respectively. The EPA requests comment on the proposed alternative emission limits. We note that all of the proposed changes discussed in this section of the preamble (*i.e.,* the proposed changes to 40 CFR 63.11960, 40 CFR 63.11985(b)(7), and 40 CFR 63.11990(h)(3)) are also being proposed for the 2012 area source rule at 40 CFR 63.11142(f)(16), (18), and (19) because 40 CFR 63.11960, 40 CFR 63.11985, and 40 CFR 63.11990 are referenced in those requirements.

TABLE 4—PROPOSED EXISTING SOURCE STRIPPED RESIN ALTERNATIVE MASS EMISSION LIMITS

Resin subcategory	40 CFR part 63, subpart HHHHHHH vinyl chloride emission limit (g/kg)	40 CFR part 63, subpart HHHHHHH non-vinyl chloride organic HAP emission limit (g/kg)	40 CFR part 63, subpart DDDDDD vinyl chloride emission limit (g/kg)	40 CFR part 63, subpart DDDDDD Non-vinyl chloride organic HAP emission limit (g/kg)
Bulk resin	0.0071	0.17	0.0071	0.17
Dispersion resin	1.3	0.24	1.5	0.32
Suspension resin	0.037	0.67	0.036	0.036
Suspension blending resin	0.14	0.50	0.14	0.50
Copolymer resin	0.79	1.9	0.79	1.9

TABLE 5—PROPOSED NEW SOURCE STRIPPED RESIN ALTERNATIVE MASS EMISSION LIMITS

Resin subcategory	40 CFR part 63, subpart HHHHHHH vinyl chloride emission limit (g/kg)	40 CFR part 63, subpart HHHHHHH non-vinyl chloride organic HAP emission limit (g/kg)	40 CFR part 63, subpart DDDDDD vinyl chloride emis-sion limit (g/kg)	40 CFR part 63, subpart DDDDDD non-vinyl chloride organic HAP emission limit (g/kg)
Bulk resin	0.0071	0.17	0.0071	0.17
Dispersion resin	0.48	0.066	1.5	0.32
Suspension resin	0.0073	0.015	0.036	0.036
Suspension blending resin	0.14	0.50	0.14	0.50
Copolymer resin	0.79	1.9	0.79	1.9

3. Clarification of Initial and Continuous Monitoring of Non-Vinyl Chloride Organic HAP

The EPA's intent for demonstrating compliance with the total non-vinyl chloride organic HAP emission limits for stripped resin within 40 CFR 63.11960(b) (and as referenced in 40 CFR 63.11142(f)(16) for area sources) is for facilities to develop and maintain a specific list of non-vinyl chloride organic HAP that are expected to be present in each grade of resin produced by the PVCPU. The current rule language in 40 CFR 63.11960(b) is potentially unclear on how this list of HAP for each resin grade is updated and used to demonstrate compliance and how this list of HAP for each resin grade relates to the list of HAP contained within Table 10 to 40 CFR part 63, subpart HHHHHHH. For example, in 40 CFR 63.11960(b), we are proposing to replace ''continuously updated'' with ''kept current'' to clarify the requirement that the facility-specific HAP list is updated after any change occurs that would impact the list of HAP for the stripped resin, such as using a new additive or changing a vendor.

In addition, as discussed in the 2012 final major and area source rules (77 FR 22868), the EPA's intent is for sources to initially and continuously test for all the HAP listed in Table 10 to 40 CFR part 63, subpart HHHHHHH, plus any additional HAP not listed in Table 10 to 40 CFR part 63, subpart HHHHHHH, but expected to be present in the resin grade due to the owner or operator's process

knowledge. That is, the facility-specific HAP list comprises the 30 HAP in Table 10 to 40 CFR part 63, subpart HHHHHHH, plus any additional HAP beyond those 30 that are expected to be present based on the resin grades produced. The EPA is proposing clarifying amendments to 40 CFR 63.11960(b) and 40 CFR 63.11960(e)(1)(i) through (iv) related to the specific HAP list, and we request comment on this clarification. Furthermore, we are proposing amendments to 40 CFR 63.11960(b)(2) that provide these clarifications on the facility-specific HAP list for sources opting to comply with the proposed alternative mass emission limits that are discussed in section III.C.2 of this preamble. Finally, we are also proposing to restructure 40 CFR 63.11960(c) to improve readability. We are proposing to remove duplicative language from 40 CFR 63.11960(c)(1)(iii) and (iv) and revise 40 CFR 63.11960(c)(2)(i) and (ii) to clarify the calculation requirements for vinyl chloride and non-vinyl chloride organic HAP.

We note that these amendments are also being proposed for the 2012 area source rule at 40 CFR 63.11142(f)(16) because 40 CFR 63.11960 is referenced in those requirements.

D. Storage Vessels

We are proposing technical corrections and clarifications related to the standards for pressure vessels, the use of vapor balancing, and the standards for fixed roof and floating roof storage vessels. See sections III.D.1, 2, and 3 of this preamble, respectively for a detailed discussion of these proposed changes.

1. Pressure Vessels

A petitioner requested that the EPA reconsider the requirements of 40 CFR 63.11910(c) and allow LDAR of all pressure vessel leaks, including from closure devices. The petitioner stated that the rule should apply LDAR as a work practice standard under CAA section 112(h) for leaks from openings on pressure vessels that are equipped with closure devices since it is ''not feasible to prescribe or enforce an emission standard.'' The petitioner stated that the best performing facilities use LDAR to manage leaks from pressure vessels and contended that an allowance to make a repair once a leak is found is a common approach for managing leaks from pressure vessels and is the only achievable approach. The petitioner also stated it interprets the 2012 final major and area source rules to be that leaks from closure devices are violations (according to 40 CFR 63.11910(c)(4)), while other pressure vessel leaks are not violations and are subject to leak repair provisions (according to 40 CFR 63.11910(c)(3)). The petitioner requested that the EPA allow for repair of leaks from closure devices greater than 500 parts per million (ppm) as a method of compliance.

In the 2012 final major and area source rules, pressure vessels in HAP service are required to operate as ''a closed system that does not vent to the atmosphere'' and each opening must be equipped with a closure device to prevent discharges to the atmosphere (40 CFR 63.11910(c)). In addition, in the 2012 final major and area source rules, all potential leak interfaces on the vessel (including closure devices) must be monitored annually for leaks. The intent of the 2012 final major and area source rules was to require that pressure vessels operate with no detectable emissions (*i.e.,* less than 500 ppm as determined using EPA Method 21 of 40 CFR part 60, appendix A–7), and that each opening, including all potential leak interfaces, on pressure vessels be monitored regularly to ensure that the pressure vessels are operating with no detectable emissions. While the 2012 final major and area source rules do require potential leak interfaces to be monitored annually for leaks using the procedures specified in the equipment leak requirements at 40 CFR 63.11915, we recognize that the 2012 final major and area source rules do not specify how 40 CFR 63.11915 would specifically apply to pressure vessels and, thus, the petitioner interpreted the rule to have two sets of leak requirements (one for closure devices and another for all other pressure vessel leaks).

The EPA is granting reconsideration of the pressure vessel standards of 40 CFR 63.11910(c) but does not agree with the petitioner's recommendations regarding LDAR. Specifically, the EPA is not allowing for repair of leaks greater than 500 ppm as a method of compliance. We are proposing to maintain the pressure vessel leak requirements of the 2012 rules, with edits for clarity; pressure vessels must operate with no detectable emissions and any release greater than 500 ppm above background is a violation. This requirement applies equally to closure device leaks and leaks from all other leak interfaces on the pressure vessel. To confirm there are no detectable emissions, we are proposing to specify (in lieu of generally pointing to the LDAR requirements in 40 CFR 63.11915) that the affected source must conduct annual monitoring of each potential leak interface and each point on the pressure vessel through which HAP could potentially be emitted, using the procedures specified in 40 CFR 63.1023(b) and (c). This approach to regulating pressure vessel leaks is similar to the Off-Site Waste and Recovery Operations NESHAP (40 CFR part 63, subpart DD), which stipulates that tank openings must be equipped with closure devices that are designed to operate with no detectable emissions (see 40 CFR 63.685(h)(2)). We also propose to streamline and combine the requirements at 40 CFR 63.11910(c)(3) and (4) for clarity. Under the proposed language, 40 CFR 63.11910(c)(3) includes the requirement to perform annual monitoring and states a leak greater than 500 ppm is a violation. We are proposing to remove certain language specific to pressure vessel closure devices (which was previously at 40 CFR 63.11910(c)(4)), because closure device leaks would be captured by the proposed language at 40 CFR 63.11910(c)(3) (*i.e.,* monitor each potential leak interface and each point on the pressure vessel through which HAP could potentially be emitted). We are also proposing to revise the language at 40 CFR 63.11890(d)(5)(iv) to apply more generally to pressure vessel leaks instead of just closure devices; this edit directly aligns with the proposed language at 40 CFR 63.11910(c)(3). In addition, we are proposing a definition of ''closure device'' at 40 CFR 63.12005 to mean a cover, cap, hatch, lid, plug, seal, valve, or other type of fitting that, when the device is secured in the closed position, prevents or reduces air emissions to the atmosphere by blocking an opening in a fixed roof storage vessel or pressure vessel.

As part of the leak monitoring revisions, we are proposing to revise 40 CFR 63.11990(b)(4) to clarify that the pressure vessel leak records must include the information already required to be reported in the pressure vessel closure device deviation report pursuant to 40 CFR 63.11985(b)(10)(i) through (v) (*e.g.,* we are proposing to keep records of the quantity of vinyl chloride and total HAP released from the closure device).

The EPA is also proposing to clarify the requirements for filling, emptying, and purging of pressure vessels at 40 CFR 63.11910(c)(1). The clarifications are based on actual operations of PVC production facilities and focus on the underlying pressure vessel standard. Importantly, we are emphasizing that the underlying standard is that each pressure vessel must be designed and operated as a closed system without emissions to the atmosphere. The

language at 40 CFR 63.11910(c)(1) stating that the vent stream during filling, emptying, and purging must meet the requirements of 40 CFR 63.11925(a) and (b) may appear to contradict the underlying standard that pressure vessels must be designed and operated as a closed system without emissions to the atmosphere.

To better explain our intent in clarifying the proposed language at 40 CFR 63.11910(c)(1), one must consider where pressure vessels are used at PVC production facilities, which is primarily for vinyl chloride storage (the monomer that is used as a reactant in the polymerization reaction to produce PVC). During filling operations, pressure vessels are designed to operate as closed systems, so there are no emissions from these sources during these periods. Once filled, pressure vessels storing vinyl chloride are emptied by routing the stored vinyl chloride to the process to be used in the polymerization reaction. Once routed to the process, process vents may be created that are subject to the process vent standards of 40 CFR 63.11925(a) and (b) which include closed vent system requirements. In the case of vent streams that contain any unreacted vinyl chloride, these streams are typically routed to a recovery system and vinyl chloride is recovered (to the extent practical) and sent back to the pressure vessel (which still operates as a closed system without emissions to the atmosphere). The remaining (noncondensable) vent stream containing small amounts of unrecovered vinyl chloride (and possibly other compounds) then must be controlled in order to comply with the process vent emission limits. This was the intent of the language in the 2012 final major and area source rules. Similarly, for purging operations, vinyl chloride is typically sent to a recovery system and the recovered vinyl chloride is then sent to a different pressure vessel also storing vinyl chloride (which operates as a closed system without emissions to the atmosphere). The remaining stream from the recovery system and the pressure vessel being purged contains small amounts of unrecovered vinyl chloride (and possibly other compounds) and must be controlled in order to comply with the process vent emission limits. Thus, excluding those emissions during filling, purging, and emptying that ultimately end up as process vents that are routed to a closed vent system and control device, there would still be no emissions to the atmosphere directly from pressure vessels. We are proposing to clarify at 40 CFR 63.11910(c)(1) that for vent streams sent to the process from pressure vessels, or purged from pressure vessels, facilities must prepare a design evaluation to demonstrate certain conditions are met and meet the requirements of 40 CFR 63.11925(a) and (b) including the closed vent system requirements. We also note that we are proposing that facilities may elect to comply with vapor balancing requirements during filling operations. Vapor balancing does not result in emissions to the atmosphere from pressure vessels and is a common equivalent control option for PVC production facilities during filling operations (vapor balancing requirements are discussed in greater detail in section III.D.2 of this preamble).

The EPA is soliciting comment on all of the proposed changes discussed in this section of the preamble (*i.e.,* the proposed changes to the pressure vessel requirements in 40 CFR 63.11910(c), 40 CFR 63.11985(b)(10), and 40 CFR 63.11990(b)(4)). We note that all of these proposed changes are also being proposed for the 2012 area source rule at 40 CFR 63.11142(f)(5), (18), and (19) because 40 CFR 63.11910, 40 CFR 63.11985, and 40 CFR 63.11990 are referenced in those requirements.

2. Vapor Balancing

A petitioner asserted that in the 2012 final major and area source rules, the EPA did not specifically allow vapor balancing as a method to control emissions from storage vessels. The petitioner stated that vapor balancing is widely used in the PVC industry, indicated that 11 PVC production facilities use vapor balancing, and claimed it is virtually impossible to unload a vinyl chloride railcar and not have any HAP emissions without using vapor balancing. The petitioner also noted that vapor balancing is allowed by the EPA in other MACT rules.

The EPA agrees with the petitioner and is granting reconsideration on allowing vapor balancing as a method to control emissions from storage vessels. The 2012 final major and area source rules do not list vapor balancing as a compliance option, but in responding to comments in the 2012 final rules (refer to *National Emission Standards for Hazardous Air Pollutants for Polyvinyl Chloride and Copolymers Production: Summary of Public Comments and Responses,* Docket Item No. EPA–HQ–OAR–2002–0037–0185), we stated that a PVC production facility may request the EPA's approval to use vapor balancing as an alternative means of emission limitation under 40 CFR 63.6(g) of the General Provisions. The EPA acknowledges that vapor balancing is a proven method to control emissions from storage vessel filling operations and is already allowed by several MACT standards including the HON (40 CFR part 63, subpart G). Therefore, the EPA is proposing vapor balancing requirements at 40 CFR 63.11910(e) to allow vapor balancing as an equivalent option to no emissions from pressure vessels during filling operations (see proposed 40 CFR 63.11910(c)) and as an optional equivalent control method for fixed roof storage vessels complying with the 95-percent control standard for HAP emissions in Table 3 to 40 CFR part 63, subpart HHHHHHH, during filling operations [12] (see proposed 40 CFR 63.11910(d)). The proposed vapor balancing requirements at 40 CFR 63.11910(e) are similar to the HON requirements and include operating, monitoring, and certification requirements and related recordkeeping requirements.

We are also proposing operating requirements for the vapor balancing system. We are proposing that vapor balancing systems be designed and operated to route vapors displaced from loading of the storage vessel to the transport vehicle (*i.e.,* railcar, tank truck, barge) from which the storage vessel is being loaded. For vapor balancing of pressure vessels, we are also proposing the transport vehicle may then be depressurized by sending the vapors to the process. We also propose that fluid transfer from a transport vehicle to a storage vessel must be performed only when the transport vehicle's vapor collection system is connected to the storage vessel vapor balancing system. We are proposing a definition of vapor balancing system at 40 CFR 63.12005 to mean a piping system that collects HAP vapors displaced from transport vehicles (*i.e.,* railcar, tank truck, barge) during storage vessel loading and routes the collected vapors to the storage vessel from which the HAP being loaded originated or to another storage vessel connected to a common header; or a piping system that collects HAP vapors

[12] We note that facilities that use vapor balancing for filling operations for fixed roof storage vessels that are required to route emissions to a closed vent system and control device to comply with the 95-percent control standard for HAP emissions must comply with this standard at all times. In other words, while vapor balancing fixed roof storage vessels during filling operations would control working loss emissions to at least the 95-percent control standard, owners or operators still have an obligation to control other emissions from these fixed roof storage vessels to 95-percent control, such as breathing losses and working losses that are not vapor balanced.

displaced from the loading of a storage vessel and routes the collected vapors to the transport vehicle from which the storage vessel is filled.

In addition, we are proposing monitoring requirements for equipment on the vapor balancing system. We are proposing that each PRD on a storage vessel, transport vehicle, and vapor return line must remain closed while the storage vessel is being filled and each PRD must be in compliance with the rule's existing PRD monitoring requirements at 40 CFR 63.11915(c) (see section III.F of this preamble for details on clarifications we are proposing for the rule's existing PRD monitoring requirements). PVC production facilities commonly use vapor balancing to unload vinyl chloride into pressure vessels, and as such, we are also proposing the vapor balancing system must operate with no detectable emissions, which is consistent with the proposed pressure vessel requirements at 40 CFR 63.11910(c)(3) (see section III.D.1 of this preamble). To confirm there are no detectable emissions, we are proposing that the affected source must conduct annual monitoring of each potential leak interface and each point on the vapor balancing system through which HAP could potentially be emitted, using the procedures specified in 40 CFR 63.1023(b) and (c).

We are also proposing certification and control requirements for transport vehicles. Prior to unloading into a storage vessel, we are proposing that vapor balancing systems be designed and operated to route vapors displaced from filling of the storage vessel to the transport vehicle (*i.e.,* railcar, tank truck, barge) from which the storage vessel is being filled. We are proposing that tank trucks and railcars must have a current certification from the U.S. Department of Transportation and barges must have current certification of vapor-tightness. To ensure the HAP that is vapor balanced from the PVC storage vessel to the transport vehicle is not simply released to the air, we are also proposing control and certification requirements for reloading and cleaning of the transport vehicle (see 40 CFR 63.11910(e)(6) and (7)).

Finally, we are proposing recordkeeping requirements at 40 CFR 63.11990(b)(7) if the affected source chooses to use this vapor balancing option.

The EPA is soliciting comment on all of the proposed changes discussed in this section of the preamble (*i.e.,* the proposed vapor balancing requirements in 40 CFR 63.11910(e) and 40 CFR 63.11990(b)(7)). We note that these proposed vapor balancing requirements are also being proposed for the 2012 area source rule at 40 CFR 63.11142(f)(5) and (19) because 40 CFR 63.11910 and 40 CFR 63.11990 are referenced in those requirements.

3. Fixed Roof and Floating Roof Storage Vessels

We are clarifying requirements for fixed roof storage vessels using closed vent systems and control devices that are being used to meet the 95-percent control standard for HAP emissions. To improve readability, we are proposing to move the requirements for fixed roof storage vessels using a closed vent system and control device to a separate paragraph at 40 CFR 63.11910(d) and clarify the corresponding requirements in Table 3 to 40 CFR part 63, subpart HHHHHHH. The 2012 final major and area source rules included the closed vent system and control device requirements as part of the fixed roof storage vessel requirements in 40 CFR 63.11910(a); however, our proposal to separate the closed vent system and control device requirements from the fixed roof storage vessel requirements provides clarity on what specific requirements apply when a storage vessel is using a closed vent system and control device versus the specific requirements that apply to a fixed roof storage vessel. In addition, instead of complying with the control device requirements for process vents, we are proposing that for each fixed roof storage vessel that vents to a closed vent system and control device, the affected source must develop a control device operating plan and operate the control device according to the plan. The proposed operating plan requirements are based on the requirements in 40 CFR part 60, subpart Kb (40 CFR 60.113b(c)), because 40 CFR part 60, subpart Kb, formed the basis of the underlying standard for fixed roof storage vessels that are routed to a closed vent system and control device. However, we are also proposing the option to allow the affected source to continue to comply with the control device requirements for process vents provided that the storage vessel is vented to a closed vent system and control device that is also used to comply with the process vent emission limits.

As an alternative for fixed roof storage vessels using a closed vent system and control device to comply with the 95-percent control standard for HAP emissions in Table 3 to 40 CFR part 63, subpart HHHHHHH, we are proposing at 40 CFR 63.11910(d)(4) that fixed roof storage vessel emissions may be routed back to the process instead of a control device. The proposed requirements at 40 CFR 63.11910(d)(4) include preparing a design evaluation to demonstrate certain conditions are met. PVC production facilities also use vapor balancing systems, and as discussed previously (see section III.D.2 of this preamble), we are proposing this as a compliance method.

Finally, to improve readability, we are proposing other miscellaneous revisions to the fixed roof storage vessel requirements at 40 CFR 63.11910(a) and the floating roof storage vessel requirements at 40 CFR 63.11910(b). These proposed edits serve to clarify the requirements and create consistency in the language, without changing the underlying standards.

The EPA is soliciting comment on all of the proposed changes discussed in this section of the preamble (*i.e.,* clarifications to the fixed roof and floating roof storage vessel requirements). We note that these proposed requirements are also being proposed for the 2012 area source rule at 40 CFR 63.11142(f)(5) because 40 CFR 63.11910 is referenced in those requirements.

E. Affected Source

Petitioners maintain that it was not feasible to comment on the revised definitions of the affected source at 40 CFR 63.11140(b) and 40 CFR 63.11870(b). The EPA is granting reconsideration on this issue. Although we are not making any changes to the definitions of the affected source in the 2012 final major and area source rules, we request public comments on these definitions for the reasons set forth in the 2012 final rules (see section III.A of the 2012 final preamble, 77 FR 22850).

F. Equipment Leaks

Following the promulgation of the 2012 final major and area source rules, the Vinyl Institute requested several clarifications on the equipment leak provisions in 40 CFR 63.11915 in a letter [13] dated April 5, 2013. The Vinyl Institute said the requirements in the 2012 final major and area source rules at 40 CFR 63.11915(a) are inconsistent with the EPA's conclusions discussed in the preamble to the 2012 final rules (77 FR 22848) because the rule text only references some of the requirements in 40 CFR part 63, subpart UU, despite the fact that the preamble to the 2012 final

[13] Refer to the letter titled *Clarification on Certain Provisions in the National Emission Standards for Hazardous Air Pollutants for Polyvinyl Chloride and Copolymer Production ("PVC MACT"),* from the Vinyl Institute to Andrea Siefers, U.S. EPA, dated April 5, 2013, available in the docket for this rulemaking (see Docket Item No. EPA–HQ–OAR–2002–0037–0560).

rules says that MACT (for equipment leaks at existing and new major sources) as well as GACT (for equipment leaks at existing and new area sources) is compliance with 40 CFR part 63, subpart UU, for all equipment in HAP service as defined in 40 CFR 63.12005. Specifically, the Vinyl Institute said that in referencing provisions of 40 CFR part 63, subpart UU, at 40 CFR 63.11915(a), the EPA excluded 40 CFR part 63, subpart UU, requirements for applicability (40 CFR 63.1019), and certain equipment, including: Pumps in light liquid service (40 CFR 63.1026), agitators in gas and vapor service and in light liquid service (40 CFR 63.1028), and open-ended valves or lines (40 CFR 63.1033). Additionally, the Vinyl Institute said the compliance options at 40 CFR 63.11915(b) are confusing and sometimes circular in relationship to the requirements in 40 CFR part 63, subpart UU. In particular, the Vinyl Institute said the compliance options at 40 CFR 63.11915(b) allowing use of either double (dual) mechanical seals or sealless pumps to comply with 40 CFR part 63, subpart UU, are redundant to compliance options already allowed in 40 CFR 63.1026; therefore, the Vinyl Institute requested that the EPA remove this redundancy from 40 CFR 63.11915(b).

The EPA agrees with the Vinyl Institute that the requirements in the 2012 final major and area source rules at 40 CFR 63.11915(a) do not properly reflect the EPA's MACT and GACT conclusions discussed in the preamble to the 2012 final rules (77 FR 22848) regarding compliance with 40 CFR part 63, subpart UU, for all equipment in HAP service as defined in 40 CFR 63.12005. Therefore, for consistency with the EPA's MACT and GACT conclusions discussed in the preamble to the 2012 final major and area source rules (77 FR 22848), we are proposing to revise 40 CFR 63.11915(a) to include the requirements from 40 CFR part 63, subpart UU, that are inadvertently missing from the 2012 final rules, including: Applicability requirements (40 CFR 63.1019(a), and (c) through (f)), requirements for pumps in light liquid service (40 CFR 63.1026), requirements for agitators in gas and vapor service and in light liquid service (40 CFR 63.1028), and requirements for open-ended valves or lines (40 CFR 63.1033).

Also, we are proposing to remove all of the requirements in 40 CFR 63.11915(b) because we have determined that these requirements were inadvertently published in the 2012 final major and area source rules in error. We agree with the Vinyl Institute that the requirements in 40 CFR 63.11915(b) are confusing, and sometimes redundant or circular, in relationship to the requirements in 40 CFR part 63, subpart UU. In fact, the preamble to the 2012 final major and area source rules (77 FR 22848) makes it clear that the ''proposed requirement (at 40 CFR 63.11915(b)) that reciprocating pumps, reciprocating and rotating compressors and agitators be equipped with double seals, or equivalent, was in error. In the final rules, we have adopted the MACT floor level of control for equipment leaks for all components (which is compliance with 40 CFR part 63, subpart UU), which gives affected sources the option of installing double seals, or equivalent, or complying with the LDAR requirements of the equipment leak standards.''

In addition, in a letter [14] dated May 27, 2020, the Vinyl Institute requested that the EPA clarify whether the 2012 final major and area source rules require a release indicator to be installed directly on each PRD. More specifically, the Vinyl Institute requested that the EPA revise 40 CFR 63.11915(c)(1)(i) to allow the installation of a release indicator in series with the PRD or in combination with other sensors and monitoring systems in series with the PRD (in lieu of requiring a release indicator be installed directly on each PRD). The Vinyl Institute argued that it is not necessary for the release indicator to be installed ''directly'' on the PRD in order to determine whether an emission release has occurred. The Vinyl Institute said facilities use a variety of sensor combinations and/or monitoring systems (that are not always installed ''directly'' on the PRD, but rather in series with the PRD) in order to determine whether an emission release from a PRD has occurred.

It was not our intent to require only direct installation of a release indicator on the PRD. Therefore, we are proposing to revise 40 CFR 63.11915(c) to clarify the PRD requirements that are beyond those required in 40 CFR part 63, subpart UU; and to clarify that a release indicator may either be installed on each PRD or installed on the associated process or piping system in such a way that it will indicate when an emission release has occurred. We are proposing that the release indicator device or system can include, but is not limited to, a rupture disk indicator, magnetic sensor, motion detector on the pressure relief valve stem, flow monitor, or pressure monitor. We are also clarifying in 40 CFR 63.11915(c)(1)(i) that the vinyl chloride monitoring system required in 40 CFR 63.11956 is not considered a release indicator for purposes of complying with 40 CFR 63.11915(c)(1)(i).

Also, although 40 CFR part 63, subpart UU, references the closed vent system requirements in 40 CFR part 63, subpart SS, we are proposing at 40 CFR 63.11915(d) that if the affected source routes emissions from equipment in HAP service through a closed vent system to a control device, or back into the process or a fuel gas system, then the affected source must comply with 40 CFR 63.11930 in lieu of the closed vent system requirements specified in 40 CFR 63.983 of subpart SS, and the recordkeeping and reporting requirements associated with 40 CFR 63.983 of subpart SS do not apply. Alternatively, we are proposing an option that allows the affected source to comply with the control device and closed vent system requirements for process vents, provided that the emissions from equipment are vented to the same closed vent system and control device that is also used to comply with the process vent emission limits. This proposed change streamlines all closed vent system requirements within the rule by preventing an owner or operator from having to comply with more than one set of closed vent system requirements (*e.g.,* the current rule requires owners or operators of equipment to comply with the closed vent system requirements at 40 CFR 63.983 pursuant to 40 CFR 63.1034, yet owners or operators of a process vent must comply with the closed vent system requirements at 40 CFR 63.11930). Also, this proposed change (*i.e.,* to comply with 40 CFR 63.11930 for affected sources that route emissions from equipment in HAP service through a closed vent system to a control device, or back into the process or a fuel gas system) would not allow the affected source to bypass the air pollution control device at any time, and if a bypass is used, then the affected source would be required to estimate and report the quantity of vinyl chloride and total HAP released (see 40 CFR 63.11930(c) and 40 CFR 63.11985(b)(10), respectively). We are proposing this change because bypassing an air pollution control device could result in a release of regulated HAP to the atmosphere and to be consistent with *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), where the court determined that standards under CAA section 112(d) must provide for compliance at

[14] Refer to the letter titled *RE: Description of Pressure Relief Device Monitoring Practices for PVC Facilities,* from the Vinyl Institute to Jennifer Caparoso, U.S. EPA, dated May 27, 2020, available in the docket for this rulemaking.

all times. We are also proposing at 40 CFR 63.11930(c) that any open-ended valve or line in the closed vent system that is equipped with a cap, blind flange, plug, or second valve which operates to seal the line at all times is not subject to the bypass requirements.

Finally, we are proposing at 40 CFR 63.11915(e) to make references that are related to startup, shutdown, and malfunction (SSM) exemptions for equipment leak requirements in 40 CFR part 63, subparts SS and UU, no longer applicable. Consistent with *Sierra Club* v. *EPA,* we are proposing standards in this rule that apply at all times. In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the court vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the court vacated the SSM exemptions contained in 40 CFR 63.6(f)(1) and (h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemptions violate the CAA's requirement that CAA section 112 standards apply continuously.

The EPA is soliciting comment on all of the proposed changes discussed in this section of the preamble (*i.e.,* proposed changes to the equipment leak requirements in 40 CFR 63.11915). We note that all of these proposed changes are also being proposed for the 2012 area source rule at 40 CFR 63.11142(f)(6) because 40 CFR 63.11915 is referenced in those requirements. Given that owners and operators are already complying with the control device and closed vent system requirements for process vents, we estimate that there would be no impact on any facility for making these changes. In other words, if the affected source chooses to route emissions from equipment in HAP service through a closed vent system to a control device (to comply with the equipment leak standards), we believe the affected source is likely to use the same existing closed vent system and control device being used to comply with the process vent standards.

G. Closed Vent Systems

We are proposing amendments to the closed vent system requirements in 40 CFR 63.11930 that clarify applicability. The requirement at 40 CFR 63.11930(a) is misleading because it states that the closed vent system requirements in 40 CFR 63.11930 are exclusively for closed vent systems used to route emissions from process vents; however, as specified elsewhere in the 2012 final major and area source rules, closed vent systems used to route emissions from other sources (*e.g.,* stripped resin, process wastewater, storage vessels) are also subject to the closed vent system requirements in 40 CFR 63.11930. Therefore, we are proposing to clarify 40 CFR 63.11930(a) to specify that if the affected source uses a closed vent system to comply with an emission limit in Table 1 or 2 to 40 CFR part 63, subpart DDDDDD, or an emission limit in Table 1, 1b, 2, 2b, or 3 to 40 CFR part 63, subpart HHHHHHH, or to comply with the requirements in 40 CFR 63.11910, 40 CFR 63.11915, or 40 CFR 63.11955, then the affected source must comply with the closed vent system requirements in 40 CFR 63.11930. In other words, our proposal makes clear that if a closed vent system is being used to comply with any of the PVC production standards (*i.e.,* the process vent, stripped resin, process wastewater, storage vessel, equipment leak, or other emission source standards in 40 CFR part 63, subpart DDDDDD or HHHHHHH), then 40 CFR 63.11930 applies. For the same reasons, we are also proposing to amend 40 CFR 63.11930(b) (*i.e.,* the requirement that each closed vent system be designed and operated to collect HAP vapors and route the collected vapors to a control device) applies to all emission sources that route emissions through a closed vent system to a control device, a fuel gas system, or process.

The EPA is soliciting comment on all of the proposed changes discussed in this section of the preamble (*i.e.,* proposed changes to the closed vent system requirements in 40 CFR 63.11930). We note that all of these proposed changes are also being proposed for the 2012 area source rule at 40 CFR 63.11142(f)(9) because 40 CFR 63.11930 is referenced in those requirements. Given that owners and operators are already complying with 40 CFR 63.11930 for emissions sources other than process vents (*e.g.,* stripped resin, process wastewater, and storage tanks), we estimate that there would be no impact on any facility for making this change.

H. Affirmative Defense

In the 2012 final major and area source rules, the EPA included an affirmative defense to civil penalties for violations caused by malfunctions (see 40 CFR 63.11895) in an effort to create a system that incorporated some flexibility, recognizing that there is a tension, inherent in many types of air regulation, to ensure adequate compliance while simultaneously recognizing that despite the most diligent of efforts, emission standards may be violated under circumstances entirely beyond the control of the source. Although the EPA recognized that its case-by-case enforcement discretion provides sufficient flexibility in these circumstances, it included the affirmative defense to provide a more formalized approach and more regulatory clarity. See *Weyerhaeuser Co.* v. *Costle,* 590 F.2d 1011, 1057–58 (D.C. Cir. 1978) (holding that an informal case-by-case enforcement discretion approach is adequate); but see *Marathon Oil Co.* v. *EPA,* 564 F.2d 1253, 1272–73 (9th Cir. 1977) (requiring a more formalized approach to consideration of ''upsets beyond the control of the permit holder.''). Under the EPA's regulatory affirmative defense provisions, if a source could demonstrate in a judicial or administrative proceeding that it had met the requirements of the affirmative defense in the regulation, civil penalties would not be assessed. However, the court vacated the affirmative defense in one of the EPA's CAA section 112 regulations. *NRDC* v. *EPA,* 749 F.3d 1055 (D.C. Cir., 2014) (vacating affirmative defense provisions in the CAA section 112 rule establishing emission standards for Portland cement kilns). The court found that the EPA lacked authority to establish an affirmative defense for private civil suits and held that under the CAA, the authority to determine civil penalty amounts in such cases lies exclusively with the courts, not the EPA. Specifically, the court found: ''As the language of the statute makes clear, the courts determine, on a case-by-case basis, whether civil penalties are 'appropriate.''' See *NRDC* at 1063 (''[U]nder this statute, deciding whether penalties are 'appropriate' in a given private civil suit is a job for the courts, not EPA.'').[15] In light of *NRDC,* the EPA is proposing to remove all of the regulatory affirmative defense provisions from 40 CFR part 63, subpart DDDDDD (*i.e.,* the reference to ''§ 63.11895'' in 40 CFR 63.11142(f)(2)), and 40 CFR part 63, subpart HHHHHHH (*i.e.,* 40 CFR 63.11895 in its entirety and all other rule text that references 40 CFR 63.11895). As explained above, if a source is unable to comply with emissions standards as a result of a malfunction, the EPA may use its case-by-case enforcement discretion to provide flexibility, as appropriate. Further, as the court recognized, in an EPA or citizen enforcement action, the court has the discretion to consider any

[15] The court's reasoning in *NRDC* focuses on civil judicial actions. The court noted that ''EPA's ability to determine whether penalties should be assessed for CAA violations extends only to administrative penalties, not to civil penalties imposed by a court.'' *Id.*

defense raised and determine whether penalties are appropriate. *Cf. NRDC,* at 1064 (arguments that violation was caused by unavoidable technology failure can be made to the courts in future civil cases when the issue arises). The same is true for the presiding officer in EPA administrative enforcement actions.[16]

I. Other Technical Corrections and Clarifications

There are a number of additional revisions that we are proposing to 40 CFR part 63, subpart DDDDDD, and 40 CFR part 63, subpart HHHHHHH, to clarify text and correct typographical errors, grammatical errors, and cross-reference errors; and we request public comment on these revisions. These proposed editorial corrections and clarifications are summarized in Table 6 of this preamble. We note that although these proposed changes are being made directly in the major source rule, many of these proposed changes also result in revisions to the area source rule because 40 CFR part 63, subpart DDDDDD, references provisions in 40 CFR part 63, subpart HHHHHHH.

TABLE 6—SUMMARY OF PROPOSED EDITORIAL AND MINOR CORRECTIONS TO 40 CFR PART 63, SUBPART DDDDDD AND 40 CFR PART 63, SUBPART HHHHHHH

40 CFR part 63, subpart HHHHHHH provision	Proposed revision	40 CFR part 63, subpart DDDDDD provision [1]
Not applicable	Replace ''are considered an existing affected source'' with ''must comply with paragraphs (b)(3)(i) and (ii) of this section'' to clarify requirements.	40 CFR 63.11140(b)(3).
40 CFR 63.11872	Revise heading to ''What is the relationship to other regulations?'' to clarify content of 40 CFR 63.11872. Clarify that 40 CFR part 63, subpart J, does not apply to any source that is subject to the requirements of this subpart. 40 CFR part 63, subpart J, was vacated by court action.	Not applicable.
40 CFR 63.11896(b)	Revise first sentence to be consistent with the same phrasing used in 40 CFR 63.11896(a).	40 CFR 63.11142(f)(3).
40 CFR 63.11900(c)	Replace ''the effective date of publication of the final rule in the **Federal Register**'' with ''compliance date specified in § 63.11875'' to clarify compliance dates.	40 CFR 63.11142(f)(4).
40 CFR 63.11900(d)	Replace ''startup date of the affected source or the effective date of publication of the final rule in the **Federal Register**, whichever is later,'' with ''compliance date specified in § 63.11875'' to clarify compliance dates.	40 CFR 63.11142(f)(4).
40 CFR 63.11920(a)(3)(iii)	Change ''Appendix A'' to ''Appendix B'' to correct typographical error	40 CFR 63.11142(f)(7).
40 CFR 63.11920(g)	Replace ''repair action level'' with ''delay of repair action level'' in two instances to clarify the requirement.	40 CFR 63.11142(f)(7).
40 CFR 63.11920(h)(4)(ii)	Change the unit of measurement for ''D_{delay}'' from ''days'' to ''hours'' to correct typographical error.	40 CFR 63.11142(f)(7).
40 CFR 63.11925(b)	Replace ''Each batch process vent, continuous process vent and miscellaneous vent,'' with ''Each process vent as defined in § 63.12005,'' to clarify the requirement applies to all process vents.	40 CFR 63.11142(f)(8).
40 CFR 63.11925(c)(1)	Remove the phrase ''upon promulgation of a performance specification for hydrogen chloride CEMS,'' because performance specification for hydrogen chloride continuous emission monitoring systems (CEMS) has been promulgated at 40 CFR part 60, appendix B, performance specification 18.	40 CFR 63.11142(f)(8).
40 CFR 63.11925(d)(2) and (3), and (e)(2).	Replace ''For each CEMS and CPMS required or that you elect . . .'' with ''For each CPMS required or CEMS that you elect . . .'' to clarify CEMS is an option.	40 CFR 63.11142(f)(8).
40 CFR 63.11925(e)(2)	Refer to 40 CFR 63.11935 in its entirety instead of only paragraphs (b) and (c) to correct typographical error.	40 CFR 63.11142(f)(8).
40 CFR 63.11925(f)	Add ''Toxic equivalency limit'' to clarify title of paragraph	40 CFR 63.11142(f)(8).
40 CFR 63.11925(g)	Remove ''continuous process vent, miscellaneous vent and batch'' to clarify the requirement applies to all process vents.	40 CFR 63.11142(f)(8).
40 CFR 63.11925(g)(2)(iii)(B)(*2*)(*ii*)	Remove ''(CHAP)'' to correct typographical error and clarify vinyl chloride is excluded for purposes of compliance with the paragraph.	40 CFR 63.11142(f)(8).
40 CFR 63.11935(b)(5)	Remove the sentence ''CEMS must record data at least once every 15 minutes.'' because it is redundant with the requirement in 40 CFR 63.11935(b)(2).	40 CFR 63.11142(f)(10).
40 CFR 63.11935(b)(6)(i)	Clarify the promulgated performance specification for HCl CEMS is 40 CFR part 60, appendix B, performance specification 18 as well as requirements of 40 CFR part 60, appendix F, procedure 6.	40 CFR 63.11142(f)(10).
40 CFR 63.11935(b)(7)(i)	Replace ''continuous emissions monitoring system'' with the proper acronym ''CEMS.''.	40 CFR 63.11142(f)(10).
40 CFR 63.11935(b)(7)(ii)	Replace ''continuous emissions monitoring system'' with the proper acronym ''CEMS.''.	40 CFR 63.11142(f)(10).
40 CFR 63.11935(d)(2)(iii)	Replace ''of'' with ''explaining'' to clarify requirement	40 CFR 63.11142(f)(10).
40 CFR 63.11935(d)(3)	Replace ''of'' with ''explaining'' to clarify requirement	40 CFR 63.11142(f)(10).
40 CFR 63.11940(b)(3)(ii)	Replace ''problems'' with ''any of the aforementioned conditions'' to clarify requirement. Replace first instance of ''like or better kind and quality as'' with ''like type or manufacturer as the old catalyst or is not as efficient as'' to clarify requirement. Replace second instance of ''like or better kind and quality as'' with ''like type or manufacturer as the old catalyst or is as efficient as or more efficient than'' to clarify requirement.	40 CFR 63.11142(f)(11).
40 CFR 63.11940(c)(2)(ii)	Add ''(100.4 degrees Fahrenheit)'' to clarify conversion of degrees Celsius in degrees Fahrenheit.	40 CFR 63.11142(f)(11).

[16] Although the *NRDC* case does not address the EPA's authority to establish an affirmative defense to penalties that are available in administrative enforcement actions, we are not including such an affirmative defense in the proposed rule. As explained above, such an affirmative defense is not necessary. Moreover, assessment of penalties for violations caused by malfunctions in administrative proceedings and judicial proceedings should be consistent. *Cf.* CAA section 113(e) (requiring both the Administrator and the court to take specified criteria into account when assessing penalties).

TABLE 6—SUMMARY OF PROPOSED EDITORIAL AND MINOR CORRECTIONS TO 40 CFR PART 63, SUBPART DDDDDD AND 40 CFR PART 63, SUBPART HHHHHHH—Continued

40 CFR part 63, subpart HHHHHHH provision	Proposed revision	40 CFR part 63, subpart DDDDDD provision [1]
40 CFR 63.11940(d)(1)	Include ''and,'' and replace ''mass'' with ''mass flow'' in first sentence to clarify requirement and remove the last sentence because it is redundant with the first sentence.	40 CFR 63.11142(f)(11).
40 CFR 63.11945(b)	Add requirement to record the process information that is necessary to document operating conditions during the test.	40 CFR 63.11142(f)(12).
40 CFR 63.11955(d)(1)	Clarify that each gasholder must be vented back into the process for reuse or routed to a closed vent system and control device meeting the requirements of 40 CFR 63.11925 through 63.11950. Most gasholders return recovered gas back to an enclosed process for reuse in the manufacturing process.	40 CFR 63.11142(f)(14).
40 CFR 63.11980(a)(1)	Replace ''maximum operating conditions'' with ''maximum representative operating conditions'' to correct typographical error.	40 CFR 63.11142(f)(17).
40 CFR 63.11985(b)(6)	Revise reference from 40 CFR 63.11990(j) to 40 CFR 63.11990(j)(2)	40 CFR 63.11142(f)(18).
40 CFR 63.11985(b)(8)(ii)	Remove entire requirement to correct typographical error	40 CFR 63.11142(f)(18).
40 CFR 63.11985(b)(10)	Remove ''but'' to correct typographical error Change ''§§ 63.11910(c)(4)'' to ''§ 63.11910(c)(3)'' to correct typographical error.	40 CFR 63.11142(f)(18).
40 CFR 63.11985(c)(1)	Add ''storage vessel'' to clarify the type of equipment inspection that a delegated agency may waive the requirement for notifications.	40 CFR 63.11142(f)(18).
40 CFR 63.11985(c)(8)	Add comma to correct typographical error	40 CFR 63.11142(f)(18).
40 CFR 63.11985(c)(9)(i) and (ii)	Replace entire paragraphs with standardized performance test reporting language.	40 CFR 63.11142(f)(18).
40 CFR 63.11990(i)(5)	Remove entire requirement to correct typographical error	40 CFR 63.11142(f)(19).
40 CFR 63.12005	Remove definition of ''Container,'' ''Corrective action plan,'' ''Operating day,'' ''Root cause analysis,'' ''Solution process,'' and ''Unloading operations'' because the terms are not used in the rule.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''Batch process vent'' and ''Continuous process vent'' to add ''be'' between ''to'' and ''routed'' to correct typographical error.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''Dispersion process'' to mean a process for producing polyvinyl chloride resin using either emulsion or microsuspension. Emulsion polymerization uses water soluble initiators and is distinguished by metering in surfactants as the reaction progresses. In microsuspension polymerization, homogenizers are first mixed with a monomer outside of the polymerization reactor and oil soluble initiators are then added before charging the reactor. These two polymerization techniques produce fine particles, typically less than 10 microns, with little or no porosity. Emulsifier levels vary but agitation is very mild compared to other PVC polymerization processes. The final product is dried to powder form. This change is being proposed to keep ''dispersion'' as a broad subcategory, as some facilities make resins using both types of processes.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''First attempt at repair'' to clarify that monitoring as specified in § 63.1023(b) and (c) may be applicable.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''Polyvinyl chloride and copolymers production process unit or PVCPU'' to clarify that finished resin product is stored in a ''vessel or storage silo'' by removing the word ''tank.''.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''Polyvinyl chloride copolymer'' to clarify that a copolymer is comprised of one or more monomers and also distinguishes these monomers from additives used for stabilization and/or particle size control. Also, remove the word ''emulsion'' and ''solution'' from the definition and clarify each process.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''Polyvinyl chloride homopolymer'' to remove the word ''emulsion'' from the definition and clarify each process.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''Process component'' to replace ''units operations'' with ''unit operation'' to correct typographical error. Revise definition of ''Process component'' to clarify that ''Process components include equipment, pressure vessels, process condensers, process tanks, recovery devices, and resin strippers, as defined in this section.''.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''Process condenser'' to clarify that can apply to batch or continuous processes.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''Product'' to mean a polymer produced using vinyl chloride monomer and varying in additives (*e.g.,* initiators, terminators, etc.); catalysts; or in the relative proportions of vinyl chloride monomer with one or more other monomers, and that is manufactured by a process unit. With respect to polymers, more than one recipe may be used to produce the same product, and there can be more than one grade of a product. Product also means a chemical that is not a polymer, which is manufactured by a process unit. By-products, isolated intermediates, impurities, wastes, and trace contaminants are not considered products. This change is being proposed to be consistent with the definitions of ''Polyvinyl chloride copolymer'' and ''Polyvinyl chloride homopolymer''.	40 CFR 63.11144(b).
40 CFR 63.12005	Revise definition of ''Repaired'' to clarify that inspections from another subpart may be applicable.	40 CFR 63.11144(b).
40 CFR 63.12005	Remove the word ''emulsion'' and ''solution processes'' from the definition of ''Type of resin'' because the term is not used in the rule.	40 CFR 63.11144(b).

TABLE 6—SUMMARY OF PROPOSED EDITORIAL AND MINOR CORRECTIONS TO 40 CFR PART 63, SUBPART DDDDDD AND 40 CFR PART 63, SUBPART HHHHHHH—Continued

40 CFR part 63, subpart HHHHHHH provision	Proposed revision	40 CFR part 63, subpart DDDDDD provision [1]
Table 5	Revise flow to/from the control device of any control device to replace ''Flow to/from the control device'' to ''Presence or absence of flow to/for the control device if flow could be intermittent,'' ''N/A'' with ''Indication of absence of flow—note that absence of flow can be determined when process is not operating using simulated flow'', ''Continuous'' with ''Episodic,'' ''N/A to ''Date and time when flow stops during process operation and when flow begins after stopping during process operation,'' and ''Date and time of flow start and stop'' to ''Time period between flow stop and start'' to clarify what operating limit to establish during the initial performance test, minimum data recording frequency, and data averaging period for compliance, respectively.	40 CFR 63.11142(f)(2), (8), (10), and (18).
Table 5	Revise regeneration stream flow to regenerative adsorber to replace ''N/A'' with ''Every 15 minutes'' to clarify minimum data recording frequency.	40 CFR 63.11142(f)(2), (8), (10), and (18).
Table 5	Revise adsorber bed temperature, minimum temperature of regenerative adsorber to replace ''N/A'' with ''Every 15 minutes during regeneration cycle'' to clarify minimum data recording frequency.	40 CFR 63.11142(f)(2), (8), (10), and (18).
Table 5	Replace ''vacuum and duratio of regeneration'' with ''vacuum and duration of regeneration'' to correct typographical error. Revise vacuum and duration of regeneration of regenerative adsorber to replace ''N/A'' with ''Every 15 minutes during regeneration cycle'' to clarify minimum data recording frequency.	40 CFR 63.11142(f)(2), (8), (10), and (18).
Table 5	Revise regeneration frequency of regenerative adsorber to replace ''N/A'' with ''Date and time of regeneration start and stop'' to clarify minimum data recording frequency.	40 CFR 63.11144(f)(2), (8), (10), and (18).
Table 5	Revise adsorber operation valve sequencing and cycle time of regenerative adsorber to replace ''N/A'' with ''Daily'' to clarify data averaging period for compliance.	40 CFR 63.11142(f)(2), (8), (10), and (18).
Table 5	Revise average adsorber bed life of non-regenerative adsorber to replace ''N/A'' with ''Adsorber bed change-out time [N/A for initial performance test],'' ''N/A'' with ''Outlet VOC concentration,'' and ''N/A'' with ''Average time for three adsorber bed change-outs'' to clarify what operating limit to establish, minimum data recording frequency, and data averaging period for compliance, respectively. Replace ''Daily until breakthrough for 3 absorber bed change-outs'' with ''Daily until breakthrough for three absorber bed change-outs'' to correct typographical error.	40 CFR 63.11142(f)(2), (8), (10), and (18).
Table 5	Revise Outlet VOC concentration of the first adsorber bed in series of non-regenerative adsorber to replace ''N/A'' with ''Outlet VOC concentration'' to clarify data recording frequency.	40 CFR 63.11142(f)(2), (8), (10), and (18).

[1] Several of the proposed revisions described in this table for 40 CFR part 63, subpart HHHHHHH, are also being proposed for 40 CFR part 63, subpart DDDDDD, because the 40 CFR part 63, subpart HHHHHHH provision, is referenced in the 40 CFR part 63, subpart DDDDDD provision, identified in this column.

IV. Summary of Cost, Environmental, and Economic Impacts

We estimate that the proposed amendments will result in HAP emissions reductions of 34 tpy with an overall total capital savings of $0.033 million and an associated total annualized cost of $0.39 million. These estimated emission reductions as well as the increase in annualized costs are a result of the proposed revisions to emission limits in the 2012 major source rule for process vents and process wastewater (there is additional operations and maintenance costs of the control equipment and steam strippers that are related to the proposed emission limits). The estimated cost savings are a result of our proposal to eliminate the process wastewater TOHAP emission limit in the 2012 major source rule (there is a decrease in initial and annual costs of testing and monitoring). The details of the cost analyses and emissions reductions estimates are provided in the memorandum, *Technical Analysis and Documentation to Support EPA's Reconsideration of 40 CFR part 63 Subpart HHHHHHH National Emission Standards for the Polyvinyl Chloride and Copolymers (PVC) Production Source Category,* which is available in the docket for this rulemaking. Estimates of the economic impacts for the proposal are estimated in terms of the annualized cost of compliance as a percent of the revenues for the six ultimate parent owners of the 14 facilities expected to incur impacts as a result of this proposal. No ultimate parent owner is expected to incur annualized cost of compliance of more than 0.003 percent of their revenues. The median cost to revenue impact is about 0.001 percent. One ultimate parent company is expected to experience a savings in compliance costs associated with the proposal. For more information on these economic impacts, refer to the *Economic Impact Analysis for the NESHAP for Polyvinyl Chloride and Copolymers Production: Reconsideration Proposal,* which is in the docket for this rulemaking.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://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 not a significant regulatory action and was, therefore, not submitted to the OMB for review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

The information collection activities in these proposed rules have been submitted for approval to OMB under the PRA, as discussed for each rule

covered by this action in sections V.C.1 and 2 of this preamble.

1. PVC Major Source NESHAP

The ICR document that the EPA prepared has been assigned EPA ICR number 2432.05. You can find a copy of the ICR in the docket for this rule (Docket ID No. EPA–HQ–OAR–2002–0037), and it is briefly summarized here.

The EPA is proposing amendments to 40 CFR part 63, subpart HHHHHHH, to address petitions for reconsideration as described in section III of this preamble. This ICR documents the recordkeeping and reporting requirements and incremental burden imposed by the proposed amendments only. In summary, there is a decrease in the burden hours and cost in this ICR due to the elimination of wastewater TOHAP testing requirements that are associated with our proposed revisions to emission limits for process wastewater.

Respondents/affected entities: Owners or operators of PVC production major source facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart HHHHHHH).

Estimated number of respondents: 14 (total).

Frequency of response: Semiannual and annual.

Total estimated burden: Reduction of 2,170 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: Savings of $388,000 (per year), which includes a savings of $134,000 annualized capital or operation and maintenance costs.

2. PVC Area Source NESHAP

The ICR document that the EPA prepared has been assigned EPA ICR number 2454.04. You can find a copy of the ICR in the docket for this rule (Docket ID No. EPA–HQ–OAR–2002–0037), and it is briefly summarized here.

The EPA is proposing amendments to 40 CFR part 63, subpart DDDDDD, to address petitions for reconsideration as described in section III of this preamble. This ICR documents the recordkeeping and reporting requirements and incremental burden imposed by the proposed amendments only. In summary, there is a decrease in the burden hours and cost in this ICR due to the elimination of wastewater TOHAP testing requirements that are associated with our proposed revisions to emission limits for process wastewater.

Respondents/affected entities: Owners or operators of PVC production area source facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart DDDDDD).

Estimated number of respondents: Three (total).

Frequency of response: Semiannual and annual.

Total estimated burden: Reduction of 340 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: Savings of $61,000 (per year), which includes a savings of $21,000 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *IRA_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than December 9, 2020. The EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. There are no small entities among those affected by this proposal.

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. While this action creates an enforceable duty on the private sector, the annual cost does not exceed $100 million or more.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial new direct effects on tribal governments, 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying to those regulatory actions that concern environmental health or safety risks that the 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 subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action does not involve any new technical standards from those contained in the 2012 final rules. Therefore, the EPA did not consider the use of any voluntary consensus standards.

The SW–846 methods included in § 63.11960 were previously approved for incorporation in that section and no changes are proposed.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The 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).

The environmental justice finding in the 2012 final major and area source rules remains relevant in this action, which seeks comments on proposed amendments to 40 CFR part 63, subparts DDDDDD and HHHHHHH, that are mainly corrections to existing rule requirements and major source emission limits raised by stakeholders.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Andrew Wheeler,

Administrator.

For the reasons set forth in the preamble, the EPA proposes to amend 40 CFR part 63 as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

Subpart DDDDDD—National Emission Standards for Hazardous Air Pollutants for Polyvinyl Chloride and Copolymers Production Area Sources

■ 2. Section 63.11140 is amended by revising paragraphs (b)(2) introductory text, (b)(3) introductory text, and (c) to read as follows:

§ 63.11140 Am I subject to this subpart?

* * * * *

(b) * * *

(2) Except as specified in paragraph (b)(3) of this section, an affected source is new if you commenced construction, or reconstruction of the affected source between October 6, 2006, and May 20, 2011.

* * * * *

(3) If you are a new affected source as specified in paragraph (b)(2) of this section that commenced construction or reconstruction between October 6, 2006, and May 20, 2011, then after April 17, 2012, you must comply with paragraphs (b)(3)(i) and (ii) of this section.

* * * * *

(c) This subpart does not apply to research and development facilities, as defined in section 112(c)(7) of the Clean Air Act.

* * * * *

■ 3. Section 63.11141 is amended by adding paragraph (f) to read as follows:

§ 63.11141 What are my compliance dates?

* * * * *

(f) All affected sources that commenced construction or reconstruction on or before May 20, 2011, must be in compliance with § 63.11142(g) by [date 3 years after date of publication of final rule in the **Federal Register**]. All affected sources that commenced construction or reconstruction after May 20, 2011, must be in compliance with § 63.11142(g) upon [date of publication of final rule in the **Federal Register**] or initial startup, whichever is later.

■ 4. Section 63.11142 is amended by revising paragraphs (b), (f) introductory text, and (f)(2) and (9) and adding paragraph (g) to read as follows:

§ 63.11142 What are the standards and compliance requirements for new and existing sources?

* * * * *

(b) Except as specified in paragraph (g) of this section, you must comply with each emission limit and standard specified in Table 1 to this subpart that applies to your existing affected source, and you must comply with each emission limit and standard specified in Table 2 to this subpart that applies to your new affected source.

* * * * *

(f) You must meet the requirements of the applicable sections of subpart HHHHHHH of this part, as specified in paragraphs (f)(1) through (19) of this section, except for the purposes of complying with this subpart, where the applicable sections of subpart HHHHHHH of this part, as specified in paragraphs (f)(1) through (19) of this section reference Table 1, 1b, 2, or 2b to subpart HHHHHHH of this part, reference is made to Table 1 or Table 2 to this subpart.

* * * * *

(2) You must comply with the requirements of § 63.11890(a) through (d).

* * * * *

(9) If you use a closed vent system to comply with paragraph (b) or (g) of this section, or to comply with the requirements in § 63.11910, § 63.11915, or § 63.11955, then you must meet the requirements of § 63.11930 for closed vent systems.

* * * * *

(g) Beginning no later than the compliance dates specified in § 63.11141(f), the emission limits for PVC-combined process vents in Tables 1 and 2 to this subpart no longer apply; instead, you must comply with the emission limits for PVC-combined process vents in Tables 1b and 2b to subpart HHHHHHH of this part. At any time before the compliance dates specified in § 63.11141(f), you may choose to comply with the emission limits for PVC-combined process vents in Tables 1b and 2b to subpart HHHHHHH of this part in lieu of the emission limits for PVC-combined process vents in Tables 1 and 2 to this subpart.

■ 5. Table 1 to subpart DDDDDD of part 63 is revised to read as follows:

TABLE 1 TO SUBPART DDDDDD OF PART 63—EMISSION LIMITS AND STANDARDS FOR EXISTING AFFECTED SOURCES

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
PVC process vents [a]	Vinyl chloride	All resin types	5.3 parts per million by volume (ppmv).
	Total hydrocarbons	All resin types	46 ppmv measured as propane.
	Total organic HAP [b]	All resin types	140 ppmv.
	Dioxins/furans (toxic equivalency basis).	All resin types	0.13 nanograms per dry standard cubic meter (ng/dscm).
PVC-combined process vents [a c]	Vinyl chloride	All resin types	0.56 ppmv.
	Total hydrocarbons	All resin types	2.3 ppmv measured as propane.
	Total organic HAP [b]	All resin types	29 ppmv.
	Dioxins/furans (toxic equivalency basis).	All resin types	0.076 ng/dscm.
Stripped resin	Vinyl chloride	Bulk resin	7.1 parts per million by weight (ppmw); or 0.0071 grams per kilogram of product resin, dry basis (g/kg).
		Dispersion resin	1,500 ppmw; or 1.5 g/kg.
		Suspension resin	36 ppmw; or 0.036 g/kg.
		Suspension blending resin	140 ppmw; or 0.14 g/kg.

TABLE 1 TO SUBPART DDDDDD OF PART 63—EMISSION LIMITS AND STANDARDS FOR EXISTING AFFECTED SOURCES—Continued

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
	Total non-vinyl chloride organic HAP.	Copolymer resin	790 ppmw; or 0.79 g/kg.
		Bulk resin	170 ppmw; or 0.17 g/kg.
		Dispersion resin	320 ppmw; or 0.32 g/kg.
		Suspension resin	36 ppmw; or 0.036 g/kg.
		Suspension blending resin	500 ppmw; or 0.50 g/kg.
		Copolymer resin	1,900 ppmw; or 1.9 g/kg.
Process Wastewater	Vinyl chloride	All resin types	2.1 ppmw.

[a] Emission limits at 3-percent oxygen, dry basis.
[b] Affected sources have the option to comply with either the total hydrocarbon limit or the total organic HAP limit.
[c] Beginning on the date specified in § 63.11141(f), these limits no longer apply; instead as specified in § 63.11142(g), the limits in Table 1b to subpart HHHHHHH of this part apply.

■ 6. Table 2 to subpart DDDDDD of Part 63 is revised to read as follows:

TABLE 2 TO SUBPART DDDDDD OF PART 63—EMISSION LIMITS AND STANDARDS FOR NEW AFFECTED SOURCES

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
PVC process vents [a]	Vinyl chloride	All resin types	5.3 parts per million by volume (ppmv).
	Total hydrocarbons	All resin types	46 ppmv measured as propane.
	Total organic HAP [b]	All resin types	140 ppmv.
	Dioxins/furans (toxic equivalency basis).	All resin types	0.13 nanograms per dry standard cubic meter (ng/dscm).
PVC-combined process vents [a c]	Vinyl chloride	All resin types	0.56 ppmv.
	Total hydrocarbons	All resin types	2.3 ppmv measured as propane.
	Total organic HAP [b]	All resin types	29 ppmv.
	Dioxins/furans (toxic equivalency basis).	All resin types	0.076 ng/dscm.
Stripped resin	Vinyl chloride	Bulk resin	7.1 parts per million by weight (ppmw); or 0.0071 grams per kilogram of product resin, dry basis (g/kg).
		Dispersion resin	1,500 ppmw, or 1.5 g/kg.
		Suspension resin	36 ppmw; or 0.036 g/kg.
		Suspension blending resin	140 ppmw; or 0.14 g/kg.
		Copolymer resin	790 ppmw; or 0.79 g/kg.
	Total non-vinyl chloride organic HAP.	Bulk resin	170 ppmw; or 0.17 g/kg.
		Dispersion resin	320 ppmw; or 0.32 g/kg.
		Suspension resin	36 ppmw; or 0.036 g/kg.
		Suspension blending resin	500 ppmw; or 0.50 g/kg.
		Copolymer resin	1,900 ppmw; or 1.9 g/kg.
Process Wastewater	Vinyl chloride	All resin types	2.1 ppmw.

[a] Emission limits at 3 percent oxygen, dry basis.
[b] Affected sources have the option to comply with either the total hydrocarbon limit or the total organic HAP limit.
[c] Beginning on the date specified in § 63.11141(f), these limits no longer apply; instead as specified in § 63.11142(g), the limits in Table 2b to subpart HHHHHHH of this part apply.

Subpart HHHHHHH—National Emission Standards for Hazardous Air Pollutant Emissions for Polyvinyl Chloride and Copolymers Production

■ 7. Section 63.11865 is revised to read as follows:

§ 63.11865 Am I subject to the requirements in this subpart?

You are subject to the requirements in this subpart if you own or operate one or more polyvinyl chloride and copolymers production process units (PVCPU) as defined in § 63.12005 that are located at, or are part of, a major source of hazardous air pollutants (HAP) emissions as defined in § 63.2. The requirements of this subpart do not apply to research and development facilities, as defined in section 112(c)(7) of the Clean Air Act.

■ 8. Section 63.11872 is revised to read as follows:

§ 63.11872 What is the relationship to other regulations?

After the applicable compliance date specified in § 63.11875(a), (b), or (c), an affected source that is also subject to the provisions of other subparts in 40 CFR part 60 or this part is required to comply with this subpart and any other applicable subparts in 40 CFR part 60 or this part, except subpart J of this part does not apply to any source that is subject to the requirements of this subpart.

■ 9. Section 63.11875 is amended by adding paragraph (e) to read as follows:

§ 63.11875 When must I comply with this subpart?

* * * * *

(e) All affected sources that commenced construction or reconstruction on or before May 20, 2011, must be in compliance with § 63.11880(d) by [date 3 years after date of publication of final rule in the **Federal Register**]. All affected sources that commenced construction or reconstruction after May 20, 2011, must be in compliance with § 63.11880(d) upon [date of publication of final rule in the **Federal Register**] or initial startup, whichever is later.

■ 10. Section 63.11880 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 63.11880 What emission limits, operating limits and standards must I meet?

(a) Except as specified in paragraph (d) of this section, you must comply with each emission limit and standard specified in Table 1 to this subpart that applies to your existing affected source, and you must comply with each emission limit and standard specified in Table 2 to this subpart that applies to your new affected source.

* * * * *

(d) Beginning no later than the compliance dates specified in § 63.11875(e), the emission limits specified in Tables 1 and 2 to this subpart no longer apply. Instead, you must comply with each emission limit and standard specified in Table 1b to this subpart that applies to your existing affected source, and you must comply with each emission limit and standard specified in Table 2b to this subpart that applies to your new affected source. At any time before the compliance dates specified in § 63.11875(e), you may choose to comply with the emission limits in Tables 1b and 2b to this subpart in lieu of the emission limits in Tables 1 and 2 to this subpart.

■ 11. Section 63.11890 is amended by revising paragraphs (d)(2) and (3) and (d)(5)(iv) to read as follows:

§ 63.11890 What are my additional general requirements for complying with this subpart?

* * * * *

(d) * * *

(2) When a performance test indicates that emissions of a pollutant in Table 1, 1b, 2, or 2b to this subpart are exceeding the emission standard for the pollutant specified in Table 1, 1b, 2, or 2b to this subpart.

(3) When a 3-hour block average from a continuous emissions monitor, as required by § 63.11925(c)(1) through (3), exceeds an emission limit in Table 1, 1b, 2, or 2b to this subpart.

* * * * *

(5) * * *

(iv) A closure device and all other leaks on a pressure vessel.

* * * * *

§ 63.11895 [Removed and Reserved]

■ 12. Section 63.11895 is removed and reserved.

■ 13. Section 63.11896 is amended by revising paragraphs (a) and (b) to read as follows:

§ 63.11896 What am I required to do if I make a process change at my affected source?

* * * * *

(a) You must demonstrate that the changed process unit or component of the affected facility is in compliance with the applicable requirements for an existing affected source. You must demonstrate initial compliance with the emission limits and establish any applicable operating limits in § 63.11880 within 180 days of the date of startup of the changed process unit or component of the affected facility. You must demonstrate compliance with any applicable work practice standards upon startup of the changed process unit or component of the affected facility.

(b) You must demonstrate that the changed process unit or component of the affected facility is in compliance with the applicable requirements for a new affected source. You must demonstrate initial compliance with the emission limits and establish any applicable operating limits in § 63.11880 within 180 days of the date of startup of the changed process unit or component of the affected facility. You must demonstrate compliance with any applicable work practice standards upon startup of the changed process unit or component of the affected facility.

* * * * *

■ 14. Section 63.11900 is amended by revising paragraphs (a), (c), and (d) to read as follows:

§ 63.11900 By what date must I conduct initial performance testing and monitoring, establish any applicable operating limits and demonstrate initial compliance with my emission limits and work practice standards?

(a) For existing affected sources, you must establish any applicable operating limits required in § 63.11880 and demonstrate initial compliance with the emission limits and standards specified in Table 1 or 1b to this subpart and Table 3 to this subpart, as applicable, no later than 180 days after the compliance date specified in § 63.11875 and according to the applicable provisions in § 63.7(a)(2).

* * * * *

(c) For new or reconstructed affected sources, you must establish any applicable operating limits required in § 63.11880, and demonstrate initial compliance with the emission limits and standards specified in Table 2 or 2b to this subpart and Table 3 to this subpart, as applicable, no later than 180 days after the compliance date specified in § 63.11875 or within 180 days after startup of the source, whichever is later, according to § 63.7(a)(2)(ix).

(d) For new and reconstructed affected sources, you must demonstrate initial compliance with any applicable work practice standards required in § 63.11880 no later than the compliance date specified in § 63.11875 and according to the applicable provisions in § 63.7(a)(2).

* * * * *

■ 15. Section 63.11910 is amended by:
■ a. Revising paragraphs (a) introductory text, (a)(1) heading, (a)(1)(ii), and (a)(2)(ii);
■ b. Removing paragraph (a)(2)(iii);
■ c. Revising paragraph (a)(3)(ii);
■ d. Adding paragraph (a)(3)(iii);
■ e. Revising paragraphs (b), (c) introductory text, and (c)(1), (3), and (4); and
■ f. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 63.11910 What are my initial and continuous compliance requirements for storage vessels?

* * * * *

(a) *Fixed roof storage vessels.* Except as specified in paragraph (d) of this section, for each fixed roof storage vessel used to comply with the requirements specified in Table 3 to this subpart, you must meet the requirements in paragraphs (a)(1) through (4) of this section.

(1) *Closure requirements.* * * *

(ii) Each opening in the fixed roof must be equipped with a cover or other type of closure device designed to operate such that when the closure device is secured in the closed position there are no visible cracks, holes, gaps, or other open spaces in the closure device or between the perimeter of the opening and the closure device.

(2) * * *

(ii) You may open closure devices or remove the fixed roof under the conditions specified in paragraphs (a)(2)(ii)(A) and (B) of this section.

(A) A closure device may be opened or the roof may be removed when needed to provide access for manual operations such as maintenance, inspection, sampling, or cleaning.

(B) Opening of a conservation vent or similar type of vent that vents to the atmosphere (or allows air to enter the storage vessel) is allowed during normal operating conditions to maintain the tank internal operating pressure within tank design specifications. Normal operating conditions that may require these devices to open are during those times when the internal pressure of the storage vessel is outside the internal pressure operating range for the storage

vessel as a result of loading or unloading operations or diurnal ambient temperature fluctuations.

(3) * * *

(ii) If you determine parts of the roof are unsafe to inspect because operating personnel would be exposed to an imminent or potential danger as a consequence of such inspection, then the requirements specified in paragraph (a)(3)(i) of this section do not apply and you must comply with the requirements specified in paragraphs (a)(3)(ii)(A) and (B) of this section.

(A) You must prepare and maintain at the plant site written documentation that identifies all parts of the fixed roof and any closure devices that are unsafe to inspect and explains why such parts are unsafe to inspect.

(B) You must develop and implement a written plan and schedule to conduct inspections the next time alternative storage capacity becomes available and the storage vessel can be emptied or temporarily removed from service, as necessary, to complete the inspection. The required inspections must be performed as frequently as practicable, but do not need to be performed more than once per calendar year. Keep a copy of the written plan and schedule at the plant site, as specified in § 63.11990(b).

(iii) Keep records of the date of each inspection, as required in paragraph (a)(3)(i) and (a)(3)(ii)(B) of this section. Provide notification of each inspection as specified in § 63.11985(c)(1).

* * * * *

(b) *Floating roof storage vessels.* For each floating roof storage vessel used to comply with the requirements specified in Table 3 to this subpart, you must meet all requirements of §§ 63.1060 through 63.1067 for internal floating roof storage vessels or external floating roof storage vessels, as applicable.

(c) *Pressure vessels.* For each pressure vessel used to comply with the requirements specified in Table 3 to this subpart, you must meet the requirements in paragraphs (c)(1) through (4) of this section.

(1) You must operate the pressure vessel as a closed system without emissions to the atmosphere. Vent streams sent to the process from pressure vessels, or purged from pressure vessels, must meet the requirements in paragraph (d)(4) of this section and § 63.11925(a) and (b). You may also elect to vapor balance the pressure vessel during filling operations and comply with the requirements in paragraph (e) of this section.

* * * * *

(3) The pressure vessel must be designed to operate with no detectable emissions, as indicated by an instrument reading of less than 500 ppm above background, at all times. Any such release (*e.g.,* leak) constitutes a violation. You must conduct annual monitoring of each potential leak interface and each point on the pressure vessel through which HAP could potentially be emitted, using the procedures specified in § 63.1023(b) and (c) and paragraphs (c)(3)(i) and (ii) of this section.

(i) When § 63.1023(b)(5) refers to ''when the equipment is in regulated material service or is in use with any other detectable material,'' it means ''when the pressure vessel is in HAP service'' for the purposes of this section.

(ii) Section 63.1023(b)(6) does not apply for the purposes of this section.

(4) You must comply with the recordkeeping provisions specified in § 63.11990(b)(4) and the reporting provisions specified in § 63.11985(a)(1) and (b)(1) and (10).

(d) *Fixed roof storage vessels vented to a closed vent system and control device.* For each fixed roof storage vessel that vents to a closed vent system and control device to comply with the requirements specified in Table 3 to this subpart, you must meet the requirements in paragraphs (a)(1) and (3) and (d)(1) through (3) of this section. In lieu of complying with the requirements specified in paragraphs (d)(1) through (3) of this section, you may elect to route emissions back to the process and comply with the requirements in paragraph (d)(4) of this section. During filling operations, in lieu of complying with the requirements specified in paragraphs (d)(1) through (3) of this section, you may elect to vapor balance the storage vessel and comply with the requirements in paragraph (e) of this section.

(1) Except as specified in paragraph (d)(2) of this section, you must develop a control device operating plan containing the information listed in paragraphs (d)(1)(i) and (ii) of this section and meet the requirements specified in § 63.11930. You must then operate the control device and monitor the parameters of the control device in accordance with the operating plan. You must not use a flare to comply with the 95 weight percent HAP reduction requirement in Table 3 to this subpart.

(i) The documentation demonstrating that the control device will achieve the required control efficiency during maximum loading conditions is to include a description of the gas stream which enters the control device, including flow and HAP content under varying liquid level conditions (dynamic and static) and manufacturer's design specifications for the control device. If the control device or the closed vent system receives vapors, gases, or liquids other than fuels from sources that are not fixed roof storage vessels, then the efficiency demonstration is to include consideration of all vapors, gases, and liquids received by the closed vent capture system and control device. If an enclosed combustion device with a minimum residence time of 0.75 seconds and a minimum temperature of 816 degrees Celsius (1,501 degrees Fahrenheit) is used to meet the 95-percent requirement, documentation that those conditions will exist is sufficient to meet the requirements of this paragraph (d)(1)(i).

(ii) A description of the parameter or parameters to be monitored to ensure that the control device will be operated in conformance with its design and an explanation of the criteria used for selection of that parameter (or parameters).

(2) If the storage vessel is vented to a closed vent system and control device that is also used to comply with the process vent emission limits in Table 1, 1b, 2, or 2b to this subpart and you are meeting the requirements in §§ 63.11925 through 63.11950 for the closed vent system and control device, then you are not required to comply with the requirements specified in paragraph (d)(1) of this section.

(3) During periods of planned routine maintenance of a control device, operate the storage vessel in accordance with paragraphs (d)(3)(i) and (ii) of this section. You must keep the records specified in § 63.11990(b)(6).

(i) Do not add material to the storage vessel during periods of planned routine maintenance.

(ii) Limit periods of planned routine maintenance for each control device to no more than 360 hours per year.

(4) If you route emissions from a storage vessel back to the process to comply with the requirements specified in Table 3 to this subpart, you must meet the requirements in paragraphs (d)(4)(i) through (iii) of this section.

(i) The HAP in the emissions must meet one or more of the conditions specified in paragraphs (d)(4)(i)(A) through (D) of this section.

(A) Recycled and/or consumed in the same manner as a material that fulfills the same function in that process;

(B) Transformed by chemical reaction into materials that are not HAP;

(C) Incorporated into a product; and/or

(D) Recovered.

(ii) To demonstrate compliance with paragraph (d)(4)(i) of this section, you

must prepare a design evaluation (or engineering assessment) that demonstrates that one or more of the conditions specified in paragraphs (d)(4)(i)(A) through (D) of this section are being met.

(iii) You must comply with the requirements of § 63.11930.

(e) *Vapor balancing.* For each storage vessel you elect to vapor balance during filling operations to comply with the requirements specified in Table 3 to this subpart, you must meet the requirements in paragraphs (e)(1) through (7) of this section.

(1) The vapor balancing system must be designed and operated to route HAP vapors displaced from loading of the storage vessel to the railcar, tank truck, or barge from which the storage vessel is filled without emissions to the atmosphere. You may depressurize the railcar, tank truck, or barge by sending the HAP vapors back to the process and meet the requirements of paragraphs (d)(4)(i) through (iii) of this section.

(2) Tank trucks and railcars must have a current certification in accordance with the U.S. Department of Transportation (DOT) qualification and maintenance requirements of 49 CFR part 180, subparts E (for cargo tanks) and F (for tank cars). Barges must have a current certification of vapor-tightness through testing in accordance with § 63.565.

(3) HAP must only be unloaded from tank trucks, railcars, or barges when vapor collection systems are connected to the storage vessel's vapor collection system.

(4) Pressure relief devices on the storage vessel, railcar, tank truck, barge, and vapor return line must not open during storage vessel loading or as a result of diurnal temperature changes (breathing losses). You must comply with the requirements in § 63.11915(c) for each pressure relief device.

(5) The vapor balancing system must be designed to operate with no detectable emissions, as indicated by an instrument reading of less than 500 ppm above background, at all times. Any such release (*e.g.,* leak) constitutes a violation of this rule. You must conduct annual monitoring of each potential leak interface and each point on the vapor balancing system through which HAP could potentially be emitted, using the procedures specified in § 63.1023(b) and (c) and paragraphs (e)(5)(i) and (ii) of this section.

(i) When § 63.1023(b)(5) refers to ''when the equipment is in regulated material service or is in use with any other detectable material,'' it means ''when the vapor balancing system is in HAP service'' for the purposes of this section.

(ii) Section 63.1023(b)(6) does not apply for the purposes of this section.

(6) Railcars, tank trucks, or barges that deliver HAP to a storage vessel must be reloaded or cleaned at a facility that utilizes one of the control techniques specified in paragraphs (e)(6)(i) through (iii) of this section.

(i) The railcar, tank truck, or barge must be connected to a closed vent system with a non-flare control device that reduces inlet emissions of HAP by 95 percent by weight or greater. Railcars, tank trucks, or barges that have materials with a maximum true vapor pressure greater than 11.1 psia must not use the option in this paragraph (e)(6)(i).

(ii) A vapor balancing system designed and operated to collect HAP vapor displaced from the tank truck, railcar, or barge during reloading must be used to route the collected HAP vapor to the storage vessel from which the liquid being transferred originated.

(iii) The railcar, tank truck, or barge must route its emissions back to the process.

(7) The owner or operator of the facility where the railcar, tank truck, or barge is reloaded or cleaned must comply with paragraphs (e)(7)(i) through (v) of this section.

(i) Submit to the owner or operator of the storage vessel and to the Administrator a written certification that the reloading or cleaning facility will meet the requirements of paragraphs (e)(7)(i) through (iv) of this section. The certifying entity may revoke the written certification by sending a written statement to the owner or operator of the storage vessel giving at least 90 days' notice that the certifying entity is rescinding acceptance of responsibility for compliance with the requirements of paragraph (e)(7) of this section.

(ii) If complying with paragraph (e)(6)(i) of this section, comply with the requirements for closed vent systems and control devices specified in paragraph (d)(1) of this section. The notification and reporting requirements in § 63.11985 do not apply to the owner or operator of the offsite cleaning or reloading facility.

(iii) If complying with paragraph (e)(6)(ii) of this section, keep the records specified in § 63.11990(b)(7)(ii).

(iv) If complying with paragraph (e)(6)(iii) of this section, comply with the requirements in paragraphs (d)(4)(i) and (iii) only and keep the records specified in § 63.11990(b)(7)(iii).

(v) After the compliance dates specified in § 63.11875 at an offsite reloading or cleaning facility subject to paragraph (e) of this section, compliance with the monitoring, recordkeeping, and reporting requirements of any other subpart of this part constitutes compliance with the monitoring, recordkeeping, and reporting requirements of paragraphs (e)(7)(ii) through (iv) of this section. You must identify in your Notification of Compliance Status report required by § 63.11985(a) the subpart to this part with which the owner or operator of the reloading or cleaning facility complies.

■ 16. Section 63.11915 is revised to read as follows:

§ 63.11915 What are my compliance requirements for equipment leaks?

For equipment in HAP service (as defined in § 63.12005), you must comply with the requirements in paragraphs (a) through (e) of this section.

(a) Except as specified in paragraphs (c) through (e) of this section, you must comply with §§ 63.1019(a) and (c) through (f) and 63.1020 through 63.1039.

(b) [Reserved]

(c) For pressure relief devices in HAP service, as defined in § 63.12005, you must meet the requirements of this paragraph (c) in addition to the requirements specified in paragraph (a) of this section. You must also comply with the recordkeeping requirements in § 63.11990(c) and the reporting requirements in § 63.11985(a)(2), (b)(2), and (c)(7).

(1) For pressure relief devices in HAP service that discharge directly to the atmosphere without first meeting the process vent emission limits in Table 1, 1b, 2, or 2b to this subpart by routing the discharge to a closed vent system and control device designed and operated in accordance with the requirements in §§ 63.11925 through 63.11950, you must install, maintain, and operate release indicators as specified in paragraphs (c)(1)(i) and (ii) of this section. Any release to the atmosphere without meeting the process vent emission limits in Table 1, 1b, 2, or 2b to this subpart, constitutes a violation. You must submit the report specified in § 63.11985(c)(7), as described in paragraph (c)(1)(iii) of this section.

(i) A release indicator must be properly installed on each pressure relief device or associated process or piping system in such a way that it will indicate when an emission release has occurred. Examples of these types of devices and systems include, but are not limited to, a rupture disk indicator, magnetic sensor, motion detector on the pressure relief valve stem, flow monitor,

or pressure monitor. A release indicator does not include any monitoring system used to meet the requirements of § 63.11956.

(ii) Each indicator must be equipped with an alert system that will notify an operator immediately and automatically when the pressure relief device is open. The alert must be located such that the signal is detected and recognized easily by an operator.

(iii) For any instance that the release indicator indicates that a pressure relief device is open, you must notify operators that a pressure release has occurred, and, within 10 days of the release, you must submit to the Administrator the report specified in § 63.11985(c)(7).

(2) Pressure relief devices in HAP service that discharge directly to a closed vent system and control device designed and operated in accordance with the requirements in §§ 63.11925 through 63.11950, are required to meet process vent emission limits in Table 1, 1b, 2, or 2b to this subpart. Any release to the atmosphere without meeting the process vent emission limits in Table 1, 1b, 2, or 2b to this subpart, constitutes a violation. You must notify operators that a pressure release has occurred, and, within 10 days of the release, you must submit to the Administrator the report specified in § 63.11985(c)(7).

(d) If you route emissions from equipment in HAP service through a closed vent system to a control device, or back into the process or a fuel gas system, then you must comply with paragraph (d)(1) or (2) of this section.

(1) Comply with § 63.1034, except you must comply with § 63.11930 in lieu of the closed vent system requirements specified in § 63.983, and the recordkeeping and reporting requirements associated with § 63.983 do not apply.

(2) If emissions from equipment are vented to a closed vent system and control device that is also used to comply with the process vent emission limits in Table 1, 1b, 2, or 2b to this subpart and you are meeting the requirements in §§ 63.11925 through 63.11950 for the closed vent system and control device, then you are not required to comply with the closed vent system and control device requirements specified in § 63.1034.

(e) The referenced provisions specified in paragraphs (e)(1) through (6) of this section do not apply when demonstrating compliance with this section.

(1) The phrase ''except during periods of start-up, shutdown and malfunction as specified in the referencing subpart'' in § 63.984(a)(1).

(2) Section 63.998(d)(3).

(3) The phrase ''may be included as part of the startup, shutdown, and malfunction plan, as required by the referencing subpart for the source, or'' from § 63.1024(f)(4)(i).

(4) The phrase ''(except periods of startup, shutdown, or malfunction)'' from § 63.1026(e)(1)(ii)(A).

(5) The phrase ''(except during periods of startup, shutdown, or malfunction)'' from § 63.1028(e)(1)(i)(A).

(6) The phrase ''(except during periods of startup, shutdown, or malfunction)'' from § 63.1031(b)(1).

■ 17. Section 63.11920 is amended by revising paragraphs (a)(3)(iii) and (g) introductory text and revising parameter ''D_{delay}'' of Equation 1 in paragraph (h)(4)(ii) to read as follows:

§ 63.11920 What are my initial and continuous compliance requirements for heat exchange systems?

(a) * * *

(3) * * *

(iii) Determine the vinyl chloride concentration (in parts per billion by weight) in the cooling water using Method 107 at 40 CFR part 61, appendix B.

* * * * *

(g) The delay of repair action level is defined as either a total strippable volatile organic compounds concentration (as methane) in the stripping gas of 39 parts per million by volume or a total strippable volatile organic compounds concentration in the cooling water of 500 parts per billion by weight or a vinyl chloride concentration in the cooling water of 500 parts per billion by weight. While you remain below the delay of repair action level, you may delay the repair of a leaking heat exchanger only if one of the conditions in paragraph (g)(1) or (2) of this section is met. If you exceed the delay of repair action level you must repair according to paragraph (e) of this section. You must determine if a delay of repair is necessary as soon as practicable, but no later than 45 days after first identifying the leak.

* * * * *

(h) * * *

(4) * * *

(ii) * * *

D_{delay} = Expected duration of the repair delay, hours.

■ 18. Section 63.11925 is amended by revising paragraphs (a), (b), (c) introductory text, (c)(1), (d) introductory text, (d)(2) through (4), (d)(5) introductory text, (d)(5)(i), (e) introductory text, (e)(2), (e)(3)(ii), (e)(4)(i), (e)(5), (f) introductory text, (g) introductory text, (g)(2)(iii)(B)(*2*)(*ii*), (g)(3), and (h) to read as follows:

§ 63.11925 What are my initial and continuous compliance requirements for process vents?

* * * * *

(a) *Emission limits.* Each process vent must meet the emission limits in Table 1, 1b, 2, or 2b to this subpart prior to the vent stream being exposed to the atmosphere. The emission limits in Table 1, 1b, 2, or 2b to this subpart apply at all times. The emission limits in Table 1, 1b, 2, or 2b to this subpart must not be met through dilution. If an applicable process vent stream at a PVCPU is comingled with a vent stream from one or more non-PVCPU sources and the comingled streams are vented through a shared control device, then each emission standard (and subsequent control device, monitoring, recordkeeping, reporting, and other requirements) to which the comingled vent stream is subject applies.

(b) *Closed vent systems and control devices.* Each process vent as defined in § 63.12005, that is in HAP service must be routed through a closed vent system to a control device. All gas streams routed to the closed vent system and control device must be for a process purpose and not for the purpose of diluting the process vent to meet the emission limits in Table 1, 1b, 2, or 2b to this subpart. Each control device used to comply with paragraph (a) of this section must meet the requirements of §§ 63.11925 and 63.11940, and all closed vent systems must meet the requirements in § 63.11930. You must not use a flare to comply with the emission limits in Table 1, 1b, 2, or 2b to this subpart.

(c) *General monitoring requirements.* Except as provided in paragraphs (c)(1) through (3) of this section, for each control device used to comply with the process vent emission limit specified in Table 1, 1b, 2, or 2b to this subpart, you must install and operate a continuous parameter monitoring system (CPMS) to monitor each operating parameter specified in § 63.11940(a) through (h) to comply with your operating limit(s) required in § 63.11880(b).

(1) Hydrogen chloride continuous emission monitoring system (CEMS). In lieu of establishing operating limits in § 63.11880(b) and using CPMS to comply with the operating limits, as specified in § 63.11940(a) through (h), new and existing sources have the option to install a hydrogen chloride CEMS to demonstrate initial and continuous compliance with the hydrogen chloride emission limit for process vents, as specified in paragraphs (d) and (e) of this section.

* * * * *

(d) *Initial compliance.* To demonstrate initial compliance with the emission limits in Table 1, 1b, 2, or 2b to this subpart, you must comply with paragraphs (d)(1) through (5) of this section.

* * * * *

(2) For each CPMS required, or CEMS that you elect to use as specified in paragraph (c) of this section, you must prepare the quality control program and site-specific performance evaluation test plan as specified in § 63.11935(b) and site-specific monitoring plan specified in § 63.11935(c), respectively.

(3) For each CPMS required, or CEMS that you elect to use as specified in paragraph (c) of this section, you must install, operate, and maintain the CEMS and CPMS as specified in § 63.11935(b) and (c), respectively, and you must conduct an initial site-specific performance evaluation test according to your site-specific monitoring plan and § 63.11935(b)(3) and (c)(4), respectively.

(4) For each emission limit for which you use a CEMS to demonstrate compliance, you must meet the requirements specified in § 63.11890(c), and you must demonstrate initial compliance with the emission limits in Table 1, 1b, 2, or 2b to this subpart based on 3-hour block averages of CEMS data collected at the minimum frequency specified in § 63.11935(b)(2) and calculated using the data reduction method specified in § 63.11935(e). For a CEMS used on a batch operation, you may use a data averaging period based on an operating block in lieu of the 3-hour averaging period.

(5) For each emission limit in Table 1, 1b, 2, or 2b to this subpart for which you do not use a CEMS to demonstrate compliance, you must meet the requirements of paragraphs (d)(5)(i) and (ii) of this section.

(i) You must conduct an initial performance test according to the requirements in § 63.11945 to demonstrate compliance with the total hydrocarbons or total organic HAP emission limit, vinyl chloride emission limit, hydrogen chloride emission limit, and dioxin/furan emission limit in Table 1, 1b, 2, or 2b to this subpart.

* * * * *

(e) *Continuous compliance.* To demonstrate continuous compliance with the emission limits in Table 1, 1b, 2, or 2b to this subpart for each process vent, you must comply with paragraphs (e)(1) through (5) of this section.

* * * * *

(2) You must operate and maintain each CPMS required, or CEMS that you elect to use in paragraph (c) of this section, as specified in § 63.11935.

(3) * * *

(ii) You must demonstrate continuous compliance with the emission limits in Table 1, 1b, 2, or 2b to this subpart based on 3-hour block averages of CEMS data collected at the minimum frequency specified in § 63.11935(b)(2), and calculated using the data reduction method specified in § 63.11935(e). You must meet the requirements specified in § 63.11890(c). For a CEMS used on a batch operation, you may use a data averaging period based on an operating block in lieu of the 3-hour averaging period.

(4) * * *

(i) You must conduct a performance test once every 5 years according to the requirements in § 63.11945 for each pollutant in Table 1, 1b, 2, or 2b to this subpart.

* * * * *

(5) Each closed vent system and control device used to comply with an emission limit in Table 1, 1b, 2, or 2b to this subpart must be operated at all times when emissions are vented to, or collected by, these systems or devices.

(f) *Toxic equivalency limit.* To demonstrate compliance with the dioxin/furan toxic equivalency emission limit specified in Table 1, 1b, 2, or 2b to this subpart, you must determine dioxin/furan toxic equivalency as specified in paragraphs (f)(1) through (3) of this section.

* * * * *

(g) *Emission profile.* You must characterize each process vent by developing an emissions profile for each contributing process vent according to paragraphs (g)(1) through (3) of this section.

* * * * *

(2) * * *

(iii) * * *

(B) * * *

(*2*) * * *

(*ii*) The total organic HAP concentration shall be computed according to Equation 1 of this section except that only the organic HAP species shall be summed. The list of organic HAP is provided in Table 2 to subpart F of this part, except vinyl chloride shall be excluded for purposes of compliance with this paragraph (g)(2)(iii)(B)(*2*)(*ii*).

* * * * *

(3) For miscellaneous process vents, the emissions profile must be determined according to paragraph (g)(2)(iv) of this section.

(h) *Process changes.* Except for temporary shutdowns for maintenance activities, if you make a process change such that, as a result of that change, you are subject to a different process vent limit in Table 1, 1b, 2, or 2b to this subpart, then you must meet the requirements of § 63.11896.

■ 19. Section 63.11930 is amended by revising paragraphs (a), (b), (c) introductory text, (c)(1)(iv), (c)(2)(i), (c)(2)(ii)(A), and (h)(3) to read as follows:

§ 63.11930 What requirements must I meet for closed vent systems?

(a) *General.* If you use a closed vent system to comply with an emission limit in Table 1, 1b, 2, 2b, or 3 to this subpart, or to comply with the requirements in § 63.11910, § 63.11915, or § 63.11955, then you must comply with the requirements in this section. However, if you operate and maintain your closed vent system in vacuum service as defined in § 63.12005, you must meet the requirements in paragraph (h) of this section and are not required to meet the requirements in paragraphs (a) through (g) of this section.

(b) *Collection of emissions.* Each closed vent system must be designed and operated to collect HAP vapors and route the collected vapors to a control device, a fuel gas system, or process.

(c) *Bypass.* For each closed vent system that contains a bypass as defined in § 63.12005 (*e.g.,* diverting a vent stream away from the control device), you must not discharge to the atmosphere through the bypass. Any such release constitutes a violation. The use of any bypass diverted to the atmosphere during a performance test invalidates the performance test. You must comply with the provisions of either paragraph (c)(1) or (2) of this section for each closed vent system that contains a bypass that could divert a vent stream to the atmosphere. Any open-ended valve or line in the closed vent system that is equipped with a cap, blind flange, plug, or second valve and that operates to seal the open end at all times is not subject to either paragraph (c)(1) or (2) of this section.

(1) * * *

(iv) For any instances where the flow indicator alarm is triggered, you must submit to the Administrator as part of your compliance report, the information specified in § 63.11985(b)(9) and (10).

(2) * * *

(i) You must visually inspect the seal or closure mechanism at least once every month to verify that the valve is maintained in the non-diverting position, and the vent stream is not diverted through the bypass. A broken seal or closure mechanism or a diverted valve constitutes a violation. You must

maintain the records specified in paragraph (g)(1)(ii) of this section.

(ii) * * *

(A) For each instance that you change the bypass valve to the diverting position, you must submit to the Administrator as part of your compliance report, the information specified in § 63.11985(b)(9) and (10).

* * * * *

(h) * * *

(3) *In vacuum service alarm records and reports.* For any incidences where a closed vent system designed to be in vacuum service is not in vacuum service, you must submit to the Administrator as part of your compliance report, the information specified in § 63.11985(b)(10).

■ 20. Section 63.11935 is amended by revising paragraphs (a), (b)(5), (b)(6)(i), (b)(7)(i) and (ii), (d) introductory text, (d)(1), (d)(2)(iii), and (d)(3) to read as follows:

§ 63.11935 What CEMS and CPMS requirements must I meet to demonstrate initial and continuous compliance with the emission standards for process vents?

(a) *General requirements for CEMS and CPMS.* You must meet the requirements in paragraph (b) of this section for each CEMS specified in § 63.11925(c) used to demonstrate compliance with the emission limits for process vents in Table 1, 1b, 2, or 2b to this subpart. You must meet the CPMS requirements in paragraph (c) of this section and establish your operating limits in paragraph (d) of this section for each operating parameter specified in Table 5 to this subpart for each process vent control device specified in § 63.11925(b) that is used to comply with the emission limits for process vents in Table 1, 1b, 2, or 2b to this subpart, except that flow indicators specified in § 63.11940(a) are not subject to the requirements of this section.

(b) * * *

(5) You must operate and maintain the CEMS in continuous operation according to the quality control program and performance evaluation test plan.

(6) * * *

(i) A hydrogen chloride CEMS must meet the requirements of 40 CFR part 60, appendix B, performance specification 18, as well as the requirements of 40 CFR part 60, appendix F, procedure 6. A dioxin/furan CEMS must meet the requirements of the promulgated performance specification for the CEMS.

* * * * *

(7) * * *

(i) You must notify the Administrator 1 month before starting use of the CEMS.

(ii) You must notify the Administrator 1 month before stopping use of the CEMS, in which case you must also conduct a performance test within 60 days of ceasing operation of the system.

* * * * *

(d) *Establish operating limit.* For each operating parameter that must be monitored in § 63.11925(c) for process vent control devices, you must establish an operating limit as specified in paragraphs (d)(1) through (4) of this section. You must establish each operating limit as an operating parameter range, minimum operating parameter level, or maximum operating parameter level as specified in Table 7 to this subpart. Where this subpart does not specify which format to use for your operating limit (*e.g.,* operating range or minimum operating level), you must determine which format is best to establish proper operation of the control device such that you are meeting the emission limits specified in Table 1, 1b, 2, or 2b to this subpart.

(1) For process vent control devices, the operating limit established for each monitored parameter specified in § 63.11940 must be based on the operating parameter values recorded during any performance test conducted to demonstrate compliance as required by § 63.11925(d)(4) and (e)(4) and may be supplemented by engineering assessments and/or manufacturer's recommendations. You are not required to conduct performance tests over the entire range of allowed operating parameter values. The established operating limit must represent the conditions for which the control device is meeting the emission limits specified in Table 1, 1b, 2, or 2b to this subpart.

(2) * * *

(iii) The rationale for the established operating limit, including any data and calculations used to develop the operating limit and a description explaining why the operating limit indicates proper operation of the control device.

* * * * *

(3) For batch processes, you may establish operating limits for individual batch emission episodes, including each distinct episode of process vent emissions or each individual type of batch process that generates wastewater, if applicable. You must provide rationale in a batch pre-compliance report as specified in § 63.11985(c)(2) instead of the notification of compliance status for the established operating limit. You must include any data and calculations used to develop the operating limits and a description explaining why each operating limit indicates proper operation of the control device during the specific batch emission episode.

* * * * *

■ 21. Section 63.11940 is amended by revising the introductory text and paragraphs (b) introductory text, (b)(3)(ii), (c) introductory text, (c)(2)(ii), (d) introductory text, (d)(1), (e) introductory text, (f), and (g) introductory text to read as follows:

§ 63.11940 What continuous monitoring requirements must I meet for control devices required to install CPMS to meet the emission limits for process vents?

As required in § 63.11925(c), you must install and operate the applicable CPMS specified in paragraphs (a) through (g) of this section for each control device you use to comply with the emission limits for process vents in Table 1, 1b, 2, or 2b to this subpart. You must monitor, record, and calculate CPMS data averages as specified in Table 7 to this subpart. Paragraph (h) of this section provides an option to propose alternative monitoring parameters or procedures.

* * * * *

(b) *Thermal oxidizer monitoring.* If you are using a thermal oxidizer to meet an emission limit in Table 1, 1b, 2, or 2b to this subpart and you are required to use CPMS as specified in § 63.11925(c), you must equip the thermal oxidizer with the monitoring equipment specified in paragraphs (b)(1) through (3) of this section, as applicable.

* * * * *

(3) * * *

(ii) You must conduct annual internal inspections of the catalyst bed to check for fouling, plugging, or mechanical breakdown. You must also inspect the bed for channeling, abrasion, and settling. If any of the aforementioned conditions are found during the annual internal inspection of the catalyst, you must replace the catalyst bed or take other corrective action consistent with the manufacturer's recommendations within 15 days or by the next time any process vent stream is collected by the control device, whichever is later. If the catalyst bed is replaced and is not of like type or manufacturer as the old catalyst or is not as efficient as the old catalyst then you must conduct a new performance test according to § 63.11945 to determine destruction efficiency. If a catalyst bed is replaced and the replacement catalyst is of like type or manufacturer as the old catalyst or is as efficient as or more efficient than the old catalyst, then a new performance test to determine destruction efficiency is not required.

(c) *Absorber and acid gas scrubber monitoring.* If you are using an absorber or acid gas scrubber to meet an emission limit in Table 1, 1b, 2, or 2b to this subpart and you are required to use CPMS as specified in § 63.11925(c), you must install the monitoring equipment specified in paragraphs (c)(1) through (3) of this section.

* * * * *

(2) * * *

(ii) If the difference in the inlet gas stream temperature and the inlet liquid stream temperature is greater than 38 degrees Celsius (100.4 degrees Fahrenheit), you may install and operate a temperature monitoring device at the scrubber gas stream exit.

* * * * *

(d) *Regenerative adsorber monitoring.* If you are using a regenerative adsorber to meet an emission limit in Table 1, 1b, 2, or 2b to this subpart and you are required to use CPMS as specified in § 63.11925(c), you must install and operate the applicable monitoring equipment listed in paragraphs (d)(1) through (5) of this section, and comply with the requirements in paragraphs (d)(6) and (7) of this section. If the adsorption system water is wastewater as defined in § 63.12005, then it is subject to the requirements of § 63.11965.

(1) For non-vacuum regeneration systems, an integrating regeneration stream flow monitoring device having an accuracy of ±10 percent and capable of recording the total regeneration stream mass flow for each regeneration cycle.

* * * * *

(e) *Non-regenerative adsorber monitoring.* If you are using a non-regenerative adsorber, or canister type system that is sent off site for regeneration or disposal, to meet an emission limit in Table 1, 1b, 2, or 2b to this subpart and you are required to use CPMS as specified in § 63.11925(c), you must install a system of dual adsorber units in series and conduct the monitoring and bed replacement as specified in paragraphs (e)(1) through (4) of this section.

* * * * *

(f) *Condenser monitoring.* If you are using a condenser to meet an emission limit in Table 1, 1b, 2, or 2b to this subpart and you are required to use CPMS as specified in § 63.11925(c), you must install and operate a condenser exit gas temperature monitoring device.

(g) *Other control devices.* If you use a control device other than those listed in this subpart to comply with an emission limit in Table 1, 1b, 2, or 2b to this subpart and you are required to use CPMS as specified in § 63.11925(c), you must comply with the requirements as specified in paragraphs (g)(1) and (2) of this section.

* * * * *

■ 22. Section 63.11945 is amended by revising paragraphs (a) and (b) introductory text to read as follows:

§ 63.11945 What performance testing requirements must I meet for process vents?

(a) *General.* For each control device used to meet the emission limits for process vents in Table 1, 1b, 2, or 2b to this subpart, you must conduct the initial and periodic performance tests required in § 63.11925(d) and (e) and as specified in § 63.11896 using the applicable test methods and procedures specified in Table 8 to this subpart and paragraphs (b) through (d) of this section.

(b) *Process operating conditions.* You must conduct performance tests under the conditions specified in paragraphs (b)(1) through (3) of this section, as applicable. You must record the process information that documents operating conditions during the test and include in such record an explanation to support how such conditions represent the conditions specified in paragraphs (b)(1) through (3) of this section. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests. In all cases, a site-specific plan must be submitted to the Administrator for approval prior to testing in accordance with § 63.7(c). The test plan must include the emission profiles described in § 63.11925(g).

* * * * *

■ 23. Section 63.11955 is amended by revising paragraph (d)(1) to read as follows:

§ 63.11955 What are my initial and continuous compliance requirements for other emission sources?

* * * * *

(d) * * *

(1) Each gasholder must be vented back into the process for reuse or routed to a closed vent system and control device meeting the requirements of §§ 63.11925 through 63.11950.

* * * * *

■ 24. Section 63.11960 is amended by:

■ a. Revising paragraphs (a), (b) introductory text, and (b)(1) introductory text;

■ b. Adding paragraph (b)(2);

■ c. Revising paragraphs (c)(1)(iii) and (iv), (c)(2) introductory text, (c)(2)(i), and (c)(2)(ii) introductory text;

■ d. Revising parameter ''C_{Gi}'' of Equation 1 in paragraph (c)(2)(ii)(A);

■ e. Revising paragraphs (c)(2)(ii)(B), (d)(3), (e)(1)(i) through (iv), and (f) introductory text;

■ f. Revising parameter ''C_i'' of Equation 2 in paragraph (f); and

■ g. Adding paragraphs (g) and (h).

The revisions and additions read as follows:

§ 63.11960 What are my initial and continuous compliance requirements for stripped resin?

(a) *Emission limits.* You must meet the applicable vinyl chloride and total non-vinyl chloride organic HAP emission limits for stripped resin specified in Table 1, 1b, 2, or 2b to this subpart.

(b) *Determination of total non-vinyl chloride organic HAP.* You must develop a facility-specific list of HAP that are expected to be present in each grade of resin produced by your PVCPU using the procedures specified for resin concentration in paragraph (b)(1) of this section or the alternative mass emission rate limit as specified in paragraph (b)(2) of this section. This list must be kept current and must be available for inspection by the Administrator. This list must include the identification of each grade of resin produced, each HAP expected to be present in that grade of resin, and the CAS number for each HAP.

(1) For the purposes of demonstrating initial and continuous compliance as required in paragraphs (c) and (d) of this section, you must meet the requirements specified in paragraphs (b)(1)(i) and (ii) of this section.

* * * * *

(2) For the purposes of demonstrating initial and continuous compliance with the alternative mass emission rates as specified in paragraphs (g) and (h) of this section, you must meet the requirements specified in paragraphs (b)(2)(i) through (iii) of this section.

(i) The process components associated with the stripped resin process must be enclosed and routed through a closed vent system meeting the requirements in §§ 63.11925 through 63.11950 for the closed vent system and control device.

(ii) You must sample the stack emissions for all Table 10 HAP (as defined in § 63.12005) using the appropriate test methods specified in Table 8 to this subpart and the procedures specified in § 63.11945.

(iii) You must also sample the stack emissions for any HAP that are not Table 10 HAP but are expected to be present based on your facility-specific list of HAP using the appropriate test methods specified in Table 8 to this

subpart and the procedures specified in § 63.11945.

(c) * * *

(1) * * *

(iii) For continuous processes, during a 24-hour sampling period, collect one grab sample at intervals of 8 hours or per grade of PVC produced, whichever is more frequent. Each sample must be taken as the resin flows out of the stripper.

(iv) For batch processes, during a 24-hour sampling period, for each batch of each resin grade produced, collect one grab sample. Each sample must be taken immediately following the completion of the stripping operation.

(2) Demonstrate initial compliance with the vinyl chloride and total non-vinyl chloride organic HAP emission limits in Table 1, 1b, 2, or 2b to this subpart as specified in paragraphs (c)(2)(i) and (ii) of this section.

(i) Calculate the vinyl chloride 24-hour arithmetic average for each stripper using the vinyl chloride measured for the grab samples collected as specified in paragraphs (c)(1)(iii) and (iv) of this section and the calculation procedure specified in either paragraph (c)(2)(ii)(A) or (B) of this section.

(ii) Calculate the total non-vinyl chloride organic HAP 24-hour arithmetic average for each stripper by first using the total non-vinyl chloride organic HAP measured for the grab samples collected as specified in paragraphs (c)(1)(iii) and (iv) of this section and the calculation procedure specified in paragraph (f) of this section to determine the total non-vinyl chloride organic HAP concentration of each sample (C_{TNVCH}). Then, use the C_{TNVCH} and the calculation procedure specified in either paragraph (c)(2)(ii)(A) or (B) of this section to calculate the total non-vinyl chloride organic HAP 24-hour arithmetic average.

(A) * * *

C_{Gi} = 24-hour average concentration of vinyl chloride or total non-vinyl chloride organic HAP in resin grade G_i, ppmw. For non-vinyl chloride organic HAP, C_{TNVCH} from paragraph (f) of this section is used as C_{Gi} for each resin grade.

* * * * *

(B) If only one resin grade was produced during the 24-hour sampling event, use the 24-hour arithmetic average vinyl chloride and total non-vinyl chloride organic HAP concentrations for the one resin grade calculated as specified in paragraphs (c)(2)(i) and (ii) of this section for each stripper or calculate the 24-hour arithmetic average vinyl chloride and total non-vinyl chloride organic HAP concentrations for all strippers used to process the one grade of resin.

(d) * * *

(3) You must demonstrate continuous compliance with the vinyl chloride and total non-vinyl chloride organic HAP emission limit for stripped resin in Table 1, 1b, 2, or 2b to this subpart as specified in paragraphs (c)(2)(i) and (ii) of this section.

(e) * * *

(1) * * *

(i) SW–846–8260B (incorporated by reference, see § 63.14) for analysis of volatile organic compounds listed in Table 10 of this subpart or the site-specific HAP list.

(ii) SW–846–8270D (incorporated by reference, see § 63.14) for analysis of semivolatile organic compounds listed in Table 10 of this subpart or the site-specific HAP list.

(iii) SW–846–8315A (incorporated by reference, see § 63.14) for analysis of aldehyde compounds listed in Table 10 of this subpart or the site-specific HAP list.

(iv) SW–846–8015C (incorporated by reference, see § 63.14) for analysis of alcohol compounds listed in Table 10 of this subpart or the site-specific HAP list.

* * * * *

(f) *Method for calculating total non-vinyl chloride organic HAP concentration.* For each stripped resin sample analyzed using the methods specified in paragraph (e) of this section, calculate the sum of the measured concentrations of each HAP analyzed as required in paragraph (b)(1) of this section by using Equation 2 to this section.

* * * * *

C_i = Concentration of individual HAP present in the stripped resin sample analyzed pursuant to paragraph (b)(1) of this section excluding vinyl chloride, in ppmw, where a value of zero should be used for any HAP concentration that is below the detection limit.

(g) *Method for calculating alternative mass emission rates.* If you elect to demonstrate initial or continuous compliance with the alternative mass emissions rates (g/kg) in Tables 1b and 2b of this subpart, calculate the mass of the HAP emitted to the atmosphere of vinyl chloride and each HAP analyzed as required in paragraph (b)(2) of this section by using Equation 3 of this section.

$$Ei = \frac{CiDiQK(10^{-6})}{Z} \text{ (Eq. 3)}$$

E_i = HAP emissions for individual HAP i, g/kg (lb/lb) product.

C_i = Concentration of HAP i according to methods found in Table 8 to this subpart and the procedures specified in § 63.11945, in ppmv. A value of zero should be used for any HAP concentration that is below the detection limit.

Di = Density of HAP i at standard conditions, kg/m^3 (lb/ft^3).

Q = Volumetric flow rate as determined by Method 2 of appendix A to part 60 of this chapter, at standard conditions, m^3/hr (ft^3/hr).

K = Unit conversion factor, 1,000 g/kg (1 lb/lb).

10^6 = Conversion factor for ppm.

Z = Production rate of dry resin, kg/hr (lb/hr).

(h) *Method for calculating total non-vinyl chloride organic HAP mass emission rates.* If you elect to demonstrate initial or continuous compliance with the alternative total non-vinyl chloride organic HAP mass emissions rates (g/kg) in Tables 1b and 2b of this subpart, calculate the sum of the mass emission rates of each HAP required in paragraph (b)(2) of this section using the results from paragraph (g) and Equation 4 of this section.

$$E_{TNVCH} = \sum_{i=1}^{n} E_i \text{ (Eq. 4)}$$

E_{TNVCH} = Mass emission rate of total non-vinyl chloride organic HAP compounds in the stripped resin sample, in g/kg product (lb/lb product).

E_i = Mass emission rate of individual HAP present in the stripped resin sample analyzed pursuant to paragraph (b)(1) of this section excluding vinyl chloride, in g/kg product (lb/lb product).

■ 25. Section 63.11965 is amended by revising paragraphs (a), (b)(1)(i), (b)(2), (c) through (e), (f) introductory text, and (f)(1)(i) and (ii) to read as follows:

§ 63.11965 What are my general compliance requirements for wastewater?

(a) *Emission limits.* You must meet the emission limits specified in Table 1, 1b, 2, or 2b to this subpart for each process wastewater stream before being mixed with any other process wastewater stream, before being exposed to the atmosphere, and before being discharged from the affected source.

(b) * * *

(1) * * *

(i) For treated process wastewater streams, you must collect process wastewater samples at the outlet of the treatment process and before the process wastewater stream is mixed with any other process wastewater stream containing vinyl chloride or total non-vinyl chloride organic HAP concentrations less than the applicable emission limits specified in Table 1, 1b, 2, or 2b to this subpart, before being exposed to the atmosphere, and before being discharged from the affected source.

* * * * *

(2) You must measure the concentration of vinyl chloride, and if applicable, total non-vinyl chloride organic HAP, using the test methods and procedures specified in § 63.11980.

(c) *Requirements for process wastewater streams that must be treated.* You must treat each process wastewater stream that has a vinyl chloride or total non-vinyl chloride organic HAP concentration equal to or greater than the applicable emission limits specified in Table 1, 1b, 2, or 2b to this subpart as determined pursuant to paragraph (b) of this section, to reduce the concentration below the applicable emission limits specified in Table 1, 1b, 2, or 2b to this subpart. You must route wastewater streams through hard-piping to the treatment process and route the vent stream from the treatment process to a closed vent system and control device meeting the requirements of §§ 63.11925 through 63.11950. You must also meet the initial and continuous compliance requirements specified in §§ 63.11970(a) and 63.11975(a) and (b).

(d) *Requirements for process wastewater streams that do not need to be treated.* For each process wastewater stream that has a vinyl chloride or total non-vinyl chloride organic HAP concentration less than the applicable emission limits specified in Table 1, 1b, 2, or 2b to this subpart as determined pursuant to paragraph (b) of this section, you must meet the initial and continuous compliance requirements specified in §§ 63.11970(b) and 63.11975(c).

(e) *Maintenance wastewater.* You must comply with the requirements specified in § 63.105(b) and (c) for maintenance wastewater containing Table 10 HAP (as defined in § 63.12005).

(f) *Determination of total non-vinyl chloride organic HAP.* If you are subject to the emission limits specified in Table 1 or 2 to this subpart, then you must develop a facility-specific list of HAP that are expected to be present in each process wastewater stream at your PVCPU and comply with paragraph (f)(1) of this section. This list must be continuously updated and must be available for inspection by the Administrator. This list must include the identification of each HAP expected to be present in each process wastewater stream, and the CAS number for each HAP.

(1) * * *

(i) You must analyze each process wastewater sample for all Table 10 HAP using the test methods specified in § 63.11980(a)(2) and (3).

(ii) You must also analyze each process wastewater sample for any HAP that are not Table 10 HAP but are expected to be present in that sample based on your facility-specific list of HAP using the appropriate test method specified in § 63.11980(a)(2).

* * * * *

■ 26. Section 63.11970 is revised to read as follows:

§ 63.11970 What are my initial compliance requirements for process wastewater?

(a) *Demonstration of initial compliance for process wastewater streams that must be treated.* For each process wastewater stream that must be treated as specified in § 63.11965(b) and (c), you must conduct an initial performance test for the wastewater treatment process, measuring the concentration of vinyl chloride, and if applicable, total non-vinyl chloride organic HAP, in the wastewater stream at the outlet of the wastewater treatment process before the wastewater is exposed to the atmosphere, mixed with any other process stream, and before being discharged from the affected facility, using the test method and procedures specified in § 63.11980(a).

(b) *Demonstration of initial compliance for process wastewater streams that are not required to be treated.* For each process wastewater stream that has a vinyl chloride or total non-vinyl chloride organic HAP concentration less than the applicable emission limits specified in Tables 1, 1b, 2, or 2b to this subpart, you must use the collection and measurement procedures specified in § 63.11965(b)(1)(ii) and (b)(2) to demonstrate initial compliance.

■ 27. Section 63.11975 is revised to read as follows:

§ 63.11975 What are my continuous compliance requirements for process wastewater?

(a) For each process wastewater stream that must be treated as specified in § 63.11965(b) and (c), you must demonstrate continuous compliance as specified in paragraph (b) of this section. For each process wastewater stream for which you initially determine in § 63.11970(b) that treatment is not required, you must demonstrate continuous compliance as specified in paragraph (c) of this section.

(b) For each process wastewater stream that must be treated according to § 63.11965(b) and (c), you must demonstrate continuous compliance with the emission limits specified in Table 1, 1b, 2, or 2b to this subpart by following the procedures specified in paragraphs (b)(1) and (2) of this section.

(1) Following your demonstration of initial compliance in § 63.11970(a), make monthly measurements of the vinyl chloride, and if applicable, total non-vinyl chloride organic HAP, concentrations using the procedures and methods specified in § 63.11965(b)(1)(i) and (b)(2).

(2) You must demonstrate continuous compliance with the emission limits in Table 1, 1b, 2, or 2b to this subpart on a monthly basis, using the monthly concentration measurement specified in paragraph (b)(1) of this section.

(c) For each wastewater stream for which you initially determine in § 63.11970(b) that treatment is not required, you must demonstrate continuous compliance as specified in paragraphs (c)(1) and (2) of this section.

(1) Conduct annual performance tests, measuring the vinyl chloride, and if applicable, total non-vinyl chloride organic HAP concentrations using the procedures and methods specified in § 63.11965(b)(1)(ii) and (b)(2).

(2) If any annual performance test conducted as specified in paragraph (c)(1) of this section results in a concentration of vinyl chloride or total non-vinyl chloride organic HAP in the process wastewater stream that is greater than or equal to the applicable emission limits in Table 1, 1b, 2, or 2b to this subpart, then you must meet the requirements of § 63.11965(c) and you must demonstrate initial and continuous compliance as specified in § 63.11970 and this section.

■ 28. Section 63.11980 is amended by revising paragraphs (a) introductory text, (a)(1), and (b) introductory text to read as follows:

§ 63.11980 What are the test methods and calculation procedures for process wastewater?

(a) *Performance test methods and procedures.* You must determine the concentration of vinyl chloride, and if applicable, total non-vinyl chloride organic HAP, using the test methods and procedures specified in paragraphs (a)(1) through (4) of this section. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(1) You must conduct performance tests during worst-case operating conditions for the PVCPU when the process wastewater treatment process is operating as close as possible to maximum representative operating conditions. If the wastewater treatment process will be operating at several different sets of operating conditions, you must supplement the testing with

additional testing, modeling, or engineering assessments to demonstrate compliance with the emission limits.

* * * * *

(b) *Method for calculating total non-vinyl chloride organic HAP concentration.* If you are subject to the emission limits specified in Table 1 or 2 to this subpart, then for each process wastewater stream analyzed using the methods specified in paragraph (a) of this section, calculate the sum of the measured concentrations of each HAP analyzed as required in § 63.11965(f)(1) by using Equation 1 to this section.

* * * * *

■ 29. Section 63.11985 is amended by:

■ a. Revising paragraphs (a)(4), (a)(7)(ii), (a)(8)(i) and (ii), (b)(4)(i) introductory text, (b)(4)(i)(A), (b)(6) through (8), (b)(10) introductory text, and (b)(10)(v);

■ b. Removing and reserving paragraph (b)(11); and

■ c. Revising paragraphs (b)(12), (c)(1), (2), and (8) and (c)(9)(i) and (ii).

The revisions read as follows:

§ 63.11985 What notifications and reports must I submit and when?

* * * * *

(a) * * *

(4) You must include the operating limit for each monitoring parameter identified for each control device used to meet the emission limits in Table 1, 1b, 2, or 2b to this subpart, as determined pursuant to § 63.11935(d). This report must include the information in § 63.11935(d)(2), as applicable.

* * * * *

(7) * * *

(ii) You must include results of the initial testing used to determine initial compliance with the stripped resin limits in Table 1, 1b, 2, or 2b to this subpart.

(8) * * *

(i) You must include an identification of each process wastewater stream subject to the requirements of this subpart, and the results of your determination for each stream as to whether it must be treated to meet the limits of Table 1, 1b, 2, or 2b to this subpart. You must also include a description of the treatment process to be used for each process wastewater stream that requires treatment.

(ii) You must include results of the initial sampling used to determine initial compliance with the vinyl chloride limits in Table 1, 1b, 2, or 2b to this subpart.

* * * * *

(b) * * *

(4) * * *

(i) Deviations using CEMS or CPMS. For each deviation from an emission limit or operating limit where a CEMS or CPMS is being used to comply with the process vent emission limits in Table 1, 1b, 2, or 2b to this subpart, you must include the information in paragraphs (b)(4)(i)(A) through (E) of this section.

(A) For CEMS, the 3-hour block average value calculated for any period when the value is higher than an emission limit in Table 1, 1b, 2, or 2b to this subpart or when the value does not meet the data availability requirements defined in § 63.11890(c).

* * * * *

(6) You must include the records specified in § 63.11990(j)(2) for other emission sources.

(7) For resin stripper operations, you must include the daily vinyl chloride and/or monthly total non-vinyl chloride organic HAP concentration or alternative mass emission rate results for each resin type produced within the PVCPU that did not meet the stripped resin emission limits in Table 1, 1b, 2, or 2b to this subpart, as applicable.

(8) For wastewater operations, you must include the results of monthly vinyl chloride and, if applicable, monthly total non-vinyl chloride organic HAP concentration results for each process wastewater stream discharged from the affected source that did not meet the process wastewater emission limits in Tables 1, 1b, 2, or 2b to this subpart.

* * * * *

(10) If any pressure vessel closure device or closed vent system that contains a bypass has directly discharged to the atmosphere, or any closed vent system that is designed to be in vacuum service and is operating and not in vacuum service, as specified in § 63.11910(c)(3) or § 63.11930(c) or (h), you must submit to the Administrator the following information:

* * * * *

(v) The measures adopted to prevent future such discharges.

* * * * *

(12) Information required by this subpart, which is submitted with a Title V periodic report, does not need to be included in a subsequent compliance report required by this subpart or subpart referenced by this subpart. The Title V report must be referenced in the compliance report required by this subpart.

* * * * *

(c) * * *

(1) *Notification of inspection.* To provide the Administrator the opportunity to have an observer present, you must notify the Administrator at least 30 days before an inspection required by § 63.11910(a)(3). If an inspection is unplanned and you could not have known about the inspection 30 days in advance, then you must notify the Administrator at least 7 days before the inspection. Notification must be made by telephone immediately followed by written documentation demonstrating why the inspection was unplanned. Alternatively, the notification including the written documentation may be made in writing and sent so that it is received by the Administrator at least 7 days before the inspection. If a delegated state or local agency is notified, you are not required to notify the Administrator. A delegated state or local agency may waive the requirement for notification of storage vessel inspections.

(2) *Batch pre-compliance report.* You must submit a batch pre-compliance report at least 6 months prior to the compliance date of this subpart (see § 63.11875) that includes a description of the test conditions, data, calculations and other information used to establish operating limits according to § 63.11935(d) for all batch operations. If you use an engineering assessment as specified in § 63.11950(i), then you must also include data or other information supporting a finding that the emissions estimation equations in § 63.11950(a) through (h) are inappropriate. If the EPA disapproves the report, then you must still be in compliance with the emission limits and work practice standards of this subpart by your compliance date. To change any of the information submitted in the report, you must notify the EPA 60 days before you implement the planned change.

* * * * *

(8) *Commencing and ceasing operation of CEMSs.* Before starting or stopping the use of CEMS, you must notify the Administrator as specified in § 63.11935(b)(7).

(9) * * *

(i) Beginning on [date 60 days after date of publication of the final rule in the **Federal Register**], within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (c)(9)(i)(A) through (C) of this section.

(A) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert)* at the time of the test. Submit the results of the performance test to the EPA via

the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). The data must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website.

(B) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(C) *Confidential business information (CBI).* If you claim some of the information submitted under paragraph (a)(1) or (2) of this section is CBI, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (c)(9)(i)(A) and (B) of this section.

(ii) Beginning on [date 60 days after date of publication of the final rule in the **Federal Register**], within 60 days after the date of completing each CEMS performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in paragraphs (c)(9)(ii)(A) through (B) of this section.

(A) *Performance evaluations of CEMS measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* Submit the results of the performance evaluation to the EPA via CEDRI, which can be accessed through the EPA's CDX. The data must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website.

(B) *Performance evaluations of CEMS measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* The results of the performance evaluation must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(C) *Confidential business information (CBI).* If you claim some of the information submitted under paragraph (a)(1) or (2) of this section is CBI, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraphs (c)(9)(ii)(A) and (B) of this section.

* * * * *

■ 30. Section 63.11990 is amended by:
■ a. Revising paragraphs (b) introductory text and (b)(4);
■ b. Adding paragraph (b)(7);
■ c. Revising paragraphs (e)(3)(ii) and (h)(2);
■ d. Adding paragraph (h)(3);
■ e. Revising paragraph (i)(4); and
■ f. Removing paragraph (i)(5).

The revisions and additions read as follows:

§ 63.11990 What records must I keep?

* * * * *

(b) *Storage vessels.* For storage vessels, you must maintain the records specified in paragraphs (b)(1) through (7) of this section.

* * * * *

(4) For each pressure vessel, you must keep records of the information specified in § 63.11985(b)(10) and paragraph (c) of this section.

* * * * *

(7) For storage vessels that use vapor balancing, you must keep the records specified in paragraphs (b)(7)(i) through (iii) of this section.

(i) A record of the certification required by § 63.11910(e)(2).

(ii) If complying with § 63.11910(e)(6)(ii), keep the records specified in paragraphs (b)(7)(ii)(A) and (B) of this section.

(A) A record of the equipment to be used and the procedures to be followed when reloading the railcar, tank truck, or barge and displacing vapors to the storage vessel from which the liquid originates.

(B) A record of each time the vapor balancing system is used to comply with § 63.11910(e)(6)(ii).

(iii) If complying with § 63.11910(e)(6)(iii), you must keep records that demonstrate one or more of the conditions specified in § 63.11910(d)(4)(i)(A) through (D) are met.

* * * * *

(e) * * *

(3) * * *

(ii) In lieu of calculating and recording the average value specified in paragraph (e)(3)(i) of this section, if all 1-hour averages specified in § 63.11935(e) demonstrate compliance with your parameter operating limit or the applicable pollutant emission limit in Table 1, 1b, 2, or 2b to this subpart for the block average period, you may record a statement that all recorded 1-hour averages met the operating limit or emission limit, as applicable, and retain for 5 years this statement and all recorded CPMS or CEMS data for the block average period.

* * * * *

(h) * * *

(2) The total quantity (pounds) of each resin grade produced per day and the total quantity of resin processed by each resin stripper or group of strippers, identified by resin type and resin grade, per day.

(3) If you elect to demonstrate initial or continuous compliance with the alternative mass emissions rates (g/kg) in Table 1b or 2b to this subpart, you must keep the records specified in paragraphs (e) through (g) of this section for process vents and closed vent systems for equipment downstream of the stripper.

(i) * * *

(4) All testing data, including monthly measurements of the concentrations of vinyl chloride, and if applicable, the concentration of total non-vinyl chloride organic HAP in each process wastewater stream required to be measured, as specified in § 63.11975.

* * * * *

■ 31. Section 63.12005 is amended by:
■ a. Removing the definition for ''Affirmative defense'';
■ b. Revising the definition for ''Batch process vent'';

■ c. Adding in alphabetical order a definition for ''Closure device'';
■ d. Removing the definition for ''Container'';
■ e. Revising the definition for ''Continuous process vent'';
■ f. Removing the definition for ''Corrective action plan'';
■ g. Revising the definitions for ''Dispersion process'' and ''First attempt at repair'';
■ h. Removing the definition for ''Operating day'';
■ i. Revising the definitions for ''Polyvinyl chloride and copolymers production process unit or PVCPU,'' ''Polyvinyl chloride copolymer,'' ''Polyvinyl chloride homopolymer,'' ''Process component,'' ''Process condenser,'' ''Process vent,'' ''Product,'' and ''PVC-combined process vent'';
■ j. Removing the definition for ''PVC-only process vent'';
■ k. Adding in alphabetical order a definition for ''PVC process vent'';
■ l. Revising the definition for ''Repaired'';
■ m. Removing the definitions for ''Root cause analysis'' and ''Solution process'';
■ n. Revising the definitions for ''Total non-vinyl chloride organic HAP'' and ''Type of resin'';
■ o. Removing the definition for ''Unloading operations''; and
■ p. Adding in alphabetical order a definition for ''Vapor balancing system.''

The revisions and additions read as follows:

§ 63.12005 What definitions apply to this subpart?

* * * * *

Batch process vent means a vent from a batch operation from a PVCPU through which a HAP-containing gas stream has the potential to be released to the atmosphere except that it is required by this subpart to be routed to a closed vent system and control device. Emissions for all emission episodes associated with the unit operation(s) are part of the batch process vent. Batch process vents also include vents with intermittent flow from continuous operations. Examples of batch process vents include, but are not limited to, vents on condensers used for product recovery, polymerization reactors, and process tanks.

* * * * *

Closure device means a cover, cap, hatch, lid, plug, seal, valve, or other type of fitting that, when the device is secured in the closed position, prevents or reduces air emissions to the atmosphere by blocking an opening in a fixed roof storage vessel or pressure vessel.

* * * * *

Continuous process vent means a vent from a continuous PVCPU operation through which a HAP-containing gas stream has the potential to be released to the atmosphere except that it is required by this subpart to be routed to a closed vent system and control device and has the following characteristics:

(1) The gas stream originates as a continuous flow from any continuous PVCPU operation during operation of the PVCPU.

(2) The discharge into the closed vent system and control device meets at least one of the following conditions:

(i) Is directly from any continuous operation.

(ii) Is from any continuous operation after passing solely (*i.e.,* without passing through any other unit operation for a process purpose) through one or more recovery devices within the PVCPU.

(iii) Is from a device recovering only mechanical energy from a gas stream that comes either directly from any continuous operation, or from any continuous operation after passing solely (*i.e.,* without passing through any other unit operation for a process purpose) through one or more recovery devices within the PVCPU.

* * * * *

Dispersion process means a process for producing polyvinyl chloride resin that is characterized by either emulsion or microsuspension polymerization. Emulsion polymerization uses water soluble initiators and is distinguished by metering in surfactants as the reaction progresses. In microsuspension polymerization, homogenizers are first mixed with a monomer outside of the polymerization reactor and oil soluble initiators are then added before charging the reactor. These two polymerization techniques produce fine particles, typically less than 10 microns, with little or no porosity. Emulsifier levels vary but agitation is very mild compared to other PVC polymerization processes. The final product is dried to powder form.

* * * * *

First attempt at repair, for the purposes of this subpart, means to take action for the purpose of stopping or reducing leakage of organic material to the atmosphere, followed by monitoring as specified in § 63.11930(f) or § 63.1023(b) and (c), as applicable, to verify whether the leak is repaired, unless the owner or operator determines by other means that the leak is not repaired.

* * * * *

Polyvinyl chloride and copolymers production process unit or PVCPU means a collection of process components assembled and connected by hard-piping or duct work, used to process raw materials and to manufacture polyvinyl chloride and/or polyvinyl chloride copolymers. A PVCPU includes, but is not limited to, polymerization reactors; resin stripping operations; resin blend tanks; resin centrifuges; resin dryers; resin product separators; recovery devices; reactant and raw material charge vessels and tanks, holding tanks, mixing and weighing tanks; finished resin product storage vessels or storage silos; finished resin product loading operations; connected ducts and piping; equipment including pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves and connectors and instrumentation systems.

Polyvinyl chloride copolymer means a synthetic thermoplastic polymer that is derived from the simultaneous polymerization of vinyl chloride and one or more additional monomers. The additional monomers are reactive with vinyl chloride and become part of the polymer chain. Additives used in polyvinyl chloride copolymer polymerization for stabilization and/or particle size control are not as reactive, do not become part of the polymer chain, and are not considered to be monomers in the polymerization process. Polyvinyl chloride copolymer is produced by different processes, including, but not limited to, suspension process, dispersion process, and suspension blending process.

Polyvinyl chloride homopolymer means a synthetic thermoplastic polymer that is derived from the polymerization of vinyl chloride and has the general chemical structure (-H2CCHCl-)n. Polyvinyl chloride homopolymer is typically a white powder or colorless granule. Polyvinyl chloride homopolymer is produced by different processes, including, but not limited to, suspension process, dispersion process, suspension blending process, and bulk process.

* * * * *

Process component means any unit operation or group of unit operations or any part of a process or group of parts of a process that are assembled to perform a specific function (*e.g.,* polymerization reactor, dryers, etc.). Process components include equipment, pressure vessels, process condensers, process tanks, recovery devices, and

resin strippers, as defined in this section.

Process condenser means a condenser whose primary purpose is to recover material as an integral part of a batch or continuous process. All condensers recovering condensate from a batch or continuous process at or above the boiling point or all condensers in line prior to a vacuum source are considered process condensers. Typically, a primary condenser or condensers in series are considered to be integral to the batch or continuous regulated process if they are capable of and normally used for the purpose of recovering chemicals for fuel value (*i.e.,* net positive heating value), use, reuse or for sale for fuel value, use or reuse. This definition does not apply to a condenser that is used to remove materials that would hinder performance of a downstream recovery device as follows:

(1) To remove water vapor that would cause icing in a downstream condenser.

(2) To remove water vapor that would negatively affect the adsorption capacity of carbon in a downstream carbon adsorber.

(3) To remove high molecular weight organic compounds or other organic compounds that would be difficult to remove during regeneration of a downstream adsorber.

* * * * *

Process vent means a vent stream that is the result of the manifolding of each and all batch process vent, continuous process vent, or miscellaneous vent resulting from the affected facility into a closed vent system and into a common header that is routed to a control device. The process vent standards apply at the outlet of the control device. A process vent is either a PVC process vent or a PVC-combined process vent.

* * * * *

Product means a polymer produced using vinyl chloride monomer and varying in additives (*e.g.,* initiators, terminators, etc.); catalysts; or in the relative proportions of vinyl chloride monomer with one or more other monomers, and that is manufactured by a process unit. With respect to polymers, more than one recipe may be used to produce the same product, and there can be more than one grade of a product. Product also means a chemical that is not a polymer, which is manufactured by a process unit. By-products, isolated intermediates, impurities, wastes, and trace contaminants are not considered products.

PVC-combined process vent means a process vent that originates from a PVCPU and is combined with one or more process vents originating from the production of vinyl chloride monomer or ethylene dichloride prior to being controlled or emitted to the atmosphere. A vent stream originating from process components associated with the stripped resin downstream of the resin stripper (*e.g.,* dryers, centrifuges, filters) is not considered a PVC-combined process vent.

PVC process vent means a process vent that originates from a PVCPU and is not combined with one or more process vents originating from the production of vinyl chloride monomer or ethylene dichloride prior to being controlled or emitted to the atmosphere. A vent stream originating from process components associated with the stripped resin downstream of the resin stripper (*e.g.,* dryers, centrifuges, filters) is not considered a PVC process vent.

* * * * *

Repaired, for the purposes of this subpart, means equipment that is adjusted or otherwise altered to eliminate a leak as defined in the applicable sections of this subpart; and unless otherwise specified in applicable provisions of this subpart or other subpart referenced by this subpart, is inspected as specified in § 63.11930(f) to verify that emissions from the equipment are below the applicable leak definition.

* * * * *

Total non-vinyl chloride organic HAP means, for the purposes of this subpart, the sum of the measured concentrations of each HAP, as calculated according to the procedures specified in §§ 63.11960(f) and 63.11980(b) or the sum of the mass emission rates of each HAP, as calculated according to the procedures specified in § 63.11960(h).

Type of resin means the broad classification of PVC homopolymer and copolymer resin referring to the basic manufacturing process for producing that resin, including, but not limited to, suspension, dispersion, suspension blending, and bulk.

Vapor balancing system means:

(1) A piping system that collects HAP vapors displaced from transport vehicles (*i.e.,* railcar, tank truck, barge) during storage vessel loading and routes the collected vapors to the storage vessel from which the HAP being loaded originated or to another storage vessel connected to a common header, without emissions to the atmosphere; or

(2) A piping system that collects HAP vapors displaced from the loading of a storage vessel and routes the collected vapors to the transport vehicle from which the storage vessel is filled, without emissions to the atmosphere.

* * * * *

■ 32. Table 1 to subpart HHHHHHH of part 63 is amended by revising the table heading and row 1.a to read as follows:

TABLE 1 TO SUBPART HHHHHHH OF PART 63—EMISSION LIMITS AND STANDARDS FOR EXISTING AFFECTED SOURCES NOT COMPLYING WITH § 63.11880(D)

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
1. PVC process vents [a]	a. Vinyl chloride	All resin types	6.0 parts per million by volume (ppmv).
* *	*	*	* *

[a] Emission limits at 3 percent oxygen, dry basis.

* * * * *

■ 33. Table 1b to subpart HHHHHHH of part 63 is added to read as follows:

TABLE 1B TO SUBPART HHHHHHH OF PART 63—EMISSION LIMITS AND STANDARDS FOR EXISTING AFFECTED SOURCES COMPLYING WITH § 63.11880(D)

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
1. PVC process vents [a].	a. Vinyl chloride	All resin types	0.85 ppmv.
	b. Total hydrocarbons	All resin types	5.1 ppmv measured as propane.
	c. Total organic HAP [b]	All resin types	22 ppmv.
	d. Hydrogen chloride	All resin types	0.64 ppmv.
	e. Dioxins/furans (toxic equivalency basis).	All resin types	0.035 ng/dscm.
2. PVC-combined process vents [a].	a. Vinyl chloride	All resin types	0.85 ppmv.
	b. Total hydrocarbons	All resin types	9.1 ppmv measured as propane.
	c. Total organic HAP [b]	All resin types	9.7 ppmv.
	d. Hydrogen chloride	All resin types	3.9 ppmv.
	e. Dioxins/furans (toxic equivalency basis).	All resin types	0.68 ng/dscm.
3. Stripped resin	a. Vinyl chloride	i. Bulk resin	7.1 ppmw; or 0.0071 grams per kilogram of product resin, dry basis (g/kg).[c]
		ii. Dispersion resin	1300 ppmw; or 1.3 g/kg.[c]
		iii. Suspension resin	37 ppmw; or 0.037 g/kg.[c]
		iv. Suspension blending resin	140 ppmw; or 0.14 g/kg.[c]
		v. Copolymer resin	790 ppmw; or 0.79 g/kg.[c]
	b. Total non-vinyl chloride organic HAP.	i. Bulk resin	170 ppmw; or 0.17 g/kg.[c]
		ii. Dispersion resin	240 ppmw; or 0.24 g/kg.[c]
		iii. Suspension resin	670 ppmw; or 0.67 g/kg.[c]
		iv. Suspension blending resin	500 ppmw; or 0.50 g/kg.[c]
		v. Copolymer resin	1900 ppmw; or 1.9 g/kg.[c]
4. Process Wastewater.	a. Vinyl chloride	All resin types	0.73 ppmw.

[a] Emission limits at 3 percent oxygen, dry basis.
[b] Total organic HAP is alternative compliance limit for THC.
[c] If you elect to comply with the g/kg alternative mass emission limit for resins, you must comply with the requirements specified in § 63.11960(b)(2).

■ 34. Table 2 to subpart HHHHHHH of part 63 is amended by revising the table heading and rows 1.a, 2.e, and 3.a.i. to read as follows:

TABLE 2 TO SUBPART HHHHHHH OF PART 63—EMISSION LIMITS AND STANDARDS FOR NEW AFFECTED SOURCES NOT COMPLYING WITH § 63.11880(D)

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
1. PVC process vents [a]	a. Vinyl chloride	All resin types	0.56 ppmv.
*	* * *	*	* *
2. PVC-combined process vents [a].	*	* *	*
	e. Dioxins/furans (toxic equivalency basis)	All resin types	0.034 ng/dscm.
3. Stripped resin	a. Vinyl chloride	i. Bulk resin	7.1 ppmw.
*	* * *	*	* *

[a] Emission limits at 3 percent oxygen, dry basis.

* * * * *

TABLE 2B TO SUBPART HHHHHHH OF PART 63—EMISSION LIMITS AND STANDARDS FOR NEW AFFECTED SOURCES COMPLYING WITH § 63.11880(D)

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
1. PVC process vents [a]	a. Vinyl chloride	All resin types	0.85 ppmv.
	b. Total hydrocarbons	All resin types	2.2 ppmv measured as propane.
	c. Total organic HAP [b]	All resin types	1.3 ppmv.
	d. Hydrogen chloride	All resin types	0.17 ppmv.
	e. Dioxins/furans (toxic equivalency basis).	All resin types	0.035 ng/dscm.
2. PVC-combined process vents [a].	a. Vinyl chloride	All resin types	0.85 ppmv.
	b. Total hydrocarbons	All resin types	2.2 ppmv measured as propane.
	c. Total organic HAP [b]	All resin types	5.9 ppmv.
	d. Hydrogen chloride	All resin types	1.4 ppmv.
	e. Dioxins/furans (toxic equivalency basis).	All resin types	0.051 ng/dscm.
3. Stripped resin	a. Vinyl chloride	i. Bulk resin	7.1 ppmw; or 0.0071 g/kg.[c]
		ii. Dispersion resin	480 ppmw; or 0.48 g/kg.[c]
		iii. Suspension resin	7.3 ppmw; or 0.0073 g/kg.[c]
		iv. Suspension blending resin	140 ppmw; or 0.14 g/kg.[c]
		v. Copolymer—all resin types	790 ppmw; or 0.79 g/kg.[c]
	b. Total non-vinyl chloride organic HAP.	i. Bulk resin	170 ppmw; or 0.17 g/kg.[c]
		ii. Dispersion resin	66 ppmw; or 0.066 g/kg.[c]
		iii. Suspension resin	15 ppmw; or 0.015 g/kg.[c]
		iv. Suspension blending resin	500 ppmw; or 0.50 g/kg.[c]
		v. Copolymer resin	1900 ppmw; or 1.9 g/kg.[c]
4. Process Wastewater	a. Vinyl chloride	All resin types	0.57 ppmw.

[a] Emission limits at 3 percent oxygen, dry basis.
[b] Total organic HAP is alternative compliance limit for THC.
[c] If you elect to comply with the g/kg alternative mass emission limit for resins, you must comply with the requirements specified in § 63.11960(b)(2).

■ 36. Table 3 to subpart HHHHHHH of part 63 is revised to read as follows:

TABLE 3 TO SUBPART HHHHHHH OF PART 63—SUMMARY OF CONTROL REQUIREMENTS FOR STORAGE VESSELS AT NEW AND EXISTING SOURCES

If the storage vessel capacity (gallons) is . . .	And the vapor pressure [a] (psia) is . . .	Then, you must use . . .
≥20,000 but <40,000	≥4	an internal or external floating roof storage vessel and meet the requirements in § 63.11910(b) or a fixed roof storage vessel vented to a closed vent system and control device achieving 95 weight percent HAP reduction and meet the requirements of § 63.11910(d).
≥40,000	≥0.75	
Any capacity	>11.1	a pressure vessel and meet the requirements of § 63.11910(c).
All other capacity and vapor pressure combinations.		a fixed roof and meet the requirements of § 63.11910(a).

[a] Maximum true vapor pressure.

■ 37. Table 4 to subpart HHHHHHH of part 63 is amended by revising the entries for ''§ 63.10(b)(2)(ii)'' and ''§ 63.10(c)(10),'' removing the entry ''63.10(c)(11), (c)(12)'' and adding the entry ''§ 63.10(c)(11), (c)(12)'' in its place, and revising the entry ''§ 63.10(d)(5)'' to read as follows:

TABLE 4 TO SUBPART HHHHHHH OF PART 63—APPLICABILITY OF THE GENERAL PROVISIONS TO PART 63

Citation	Subject	Applies to subpart HHHHHHH	Comment
* *	* * *	*	*
§ 63.10(b)(2)(ii)	Recordkeeping of malfunctions	No	
* *	* * *	*	*
§ 63.10(c)(10)	Recording nature and cause of malfunctions	No	

TABLE 4 TO SUBPART HHHHHHH OF PART 63—APPLICABILITY OF THE GENERAL PROVISIONS TO PART 63—Continued

Citation	Subject	Applies to subpart HHHHHHH	Comment
§ 63.10(c)(11), (c)(12)	Recording corrective actions	No	
* *	* * *	*	*
§ 63.10(d)(5)	SSM reports	No	
* *	* * *	*	*

■ 38. Table 5 to subpart HHHHHHH of part 63 is amended by:

■ a. Removing the entry for ''Flow to/from the control device'' and adding the entry ''Presence or absence of flow to/from the control device if flow could be intermittent'' in its place;

■ b. Revising the entries for ''Regeneration stream flow'' and ''Adsorber bed temperature'' (both entries);

■ c. Removing the entry ''Vacuum and duratio of regeneration'' and adding the entry ''Vacuum and duration of regeneration'' in its place;

■ d. Revising the entries ''Regeneration frequency,'' ''Adsorber operation valve sequencing and cycle time,'' ''Average adsorber bed life,'' and ''Outlet VOC concentration of the first adsorber bed in series.''

The additions and revisions read as follows:

TABLE 5 TO SUBPART HHHHHHH OF PART 63—OPERATING PARAMETERS, OPERATING LIMITS AND DATA MONITORING, RECORDING AND COMPLIANCE FREQUENCIES FOR PROCESS VENTS

For these control devices, you must monitor these operating parameters . . .	Establish the following operating limit during your initial performance test . . .	Monitor, record, and demonstrate continuous compliance using these minimum frequencies		
		Data measurement	Data recording	Data averaging period for compliance
*	* *	*	* *	*
Presence or absence of flow to/from the control device if flow could be intermittent.	Indication of absence of flow—note that absence of flow can be determined when process is not operating using simulated flow.	Episodic	Date and time when flow stops during process operation and when flow begins after stopping during process operation.	Time period between flow stop and start.
*	* *	*	* *	*
Regeneration stream flow	Minimum total flow per regeneration cycle.	Continuous	Every 15 minutes	Total flow for each regeneration cycle.
Adsorber bed temperature	Maximum temperature	Continuously after regeneration and within 15 minutes of completing any temperature regulation.	Every 15 minutes after regeneration and within 15 minutes of completing any temperature regulation.	3-hour block average.
Adsorber bed temperature	Minimum temperature	Continuously during regeneration except during any temperature regulating portion of the regeneration cycle.	Every 15 minutes during regeneration cycle.	Average of regeneration cycle.
Vacuum and duration of regeneration.	Minimum vacuum and period of time for regeneration.	Continuous	Every 15 minutes during regeneration cycle.	Average vacuum and duration of regeneration.
Regeneration frequency	Minimum regeneration frequency and duration.	Continuous	Date and time of regeneration start and stop.	Date and time of regeneration start and stop.
Adsorber operation valve sequencing and cycle time.	Correct valve sequencing and minimum cycle time.	Daily	Daily	Daily
*	* *	*	* *	*
Average adsorber bed life	Adsorber bed change-out time [N/A for initial performance test].	Daily until breakthrough for three adsorber bed change-outs.	Outlet VOC concentration	Average time for three adsorber bed change-outs
Outlet VOC concentration of the first adsorber bed in series.	Limits in Table 1, 1b, 2, or 2b of this subpart.	Daily, except monthly (if more than 2 months bed life remaining) or weekly (if more than 2 weeks bed life remaining).	Outlet VOC concentration	Daily, weekly, or monthly.
*	* *	*	* *	*

■ 39. Table 8 to subpart HHHHHHH of part 63 amended by revising the heading to the first column and row 6.c to read as follows:

TABLE 8 TO SUBPART HHHHHHH OF PART 63—METHODS AND PROCEDURES FOR CONDUCTING PERFORMANCE TESTS FOR PROCESS VENTS

For each control device used to meet the emission limit in Table 1, 1b, 2, or 2b to this subpart for the following pollutant . . .	You must . . .	Using . . .
* *	* * * * *	
6. Any pollutant from a continuous, batch, or combination of continuous and batch process vent(s).	* * * * *	
	c. Conduct gas molecular weight analysis and correct concentrations the specified percent oxygen in Table 1, 1b, 2, or 2b to this subpart.	Method 3, 3A, or 3B at 40 CFR part 60, appendix A–2, using the same sampling site and time as HAP samples.
* *	* * * * *	

* * * * *

■ 40. Table 9 to subpart HHHHHHH of part 63 is amended by revising rows 3 and 4 to read as follows:

TABLE 9 TO SUBPART HHHHHHH OF PART 63—PROCEDURES FOR CONDUCTING SAMPLING OF STRIPPED RESIN AND PROCESS WASTEWATER

For demonstrating . . .	For the following emission points and types of processes . . .	Collect samples according to the following schedule . . .	
		Vinyl chloride . . .	Total non-vinyl chloride organic HAP . . .
* *	*	* *	* *
3. Initial compliance	N/A	1 grab or composite sample	1 grab or composite sample.
4. Continuous compliance	N/A	1 grab or composite sample per month	1 grab or composite sample per month.

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